CENTERS FOR MEDICARE AND MEDICAID SERVICES

PRACTICING PHYSICIANS ADVISORY COUNCIL

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Room 705A
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Council Members

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DR. JOE W. JOHNSON
DR. CHRISTOPHER LEGGETT
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Public Witnesses

ALBERT BOTHE, JR., M.D.
American Association of Medical Colleges

CAROL MONACO
American Osteopathic Association

WILLIAM G. PLESTED III, M.D.
American Medical Association

DANA TREVAS, Rapporteur

A G E N D A

Morning

Afternoon

Open Meeting

Dr. Castellanos: We're going to try to get started now. There's a request for everybody who has a cell phone or a blackberry to turn it off because of the interference. So if you could do that, at least while we're doing the meeting. You can open it up during the breaks. Good morning. I'm Dr. Ronald Castellanos, Chairman of the Practicing Physicians Advisory Council. And it's my pleasure to welcome you to the occasion of the 52nd meeting of the Council. I'd like to extend a welcome to my colleagues and fellow Council members. I appreciate your participation in this very important meeting. And I value your considered input and guidance on the various issues that will be presented today. As you look at today's agenda, you'll see the issues that will be presented to us today for consideration. The topics include Recovery Ordered Contracts, The National Provider Identifier, the Part D Prescription Drug Program, the Competitive Acquisition for Drugs, and a New Aspect of Pay for Performance Initiative Quality Indicators. I'm confident that you'll give our presenters the benefit of your practical knowledge and insight. Having successfully completed one round as chairperson in March 7th of the PPAC meeting, I'm eager to get started with this very ambitious agenda that we have before us today. Now I'd like to thank all of you for being here today. We look forward to a very productive session and a discussion of the issues relative to the various Medicare Programs. These are very exciting and challenging times in addressing issues in our healthcare delivery system. Now it's my pleasure to ask Mr. Herb Kuhn, Director of the Center for Medicare Management, Centers for Medicare and Medicaid Services to welcome you.

Welcome

Mr. Kuhn: Thanks Dr. Castellanos. And welcome again to all of you for being here. In particular I want to thank all those that traveled a long way to get here, but also to our new panel members. We have two new ones and one returning. Dr. Johnson thank you for agreeing to re-up your and serve again on the committee again. We appreciate that very much. And Dr. Przyblski, glad that you're here and joining us for your first meeting. We look forward to your full participation as we move forward in this program, so thank you all. I don't have a whole lot of comments other than to say welcome or glad you're here, but also just to thank all the members of the committee over this past quarter that we've been separated since our last meeting for the good feedback that we received from all of you in terms of agenda items, of issues, of how we can make this meeting more effectively for not only us at CMS but for you as well. I particularly want

to thank Dr. Castellanos for kind of spearheading that effort, and keeping his thumb in our side to make sure that we are listening to the committee members, and we are trying to create as robust an agenda as possible. So thank you, Dr. Castellanos and all of you for giving us thoughts on this agenda. I think as you heard from him on the agenda, those who have looked at the agenda, it's a pretty full agenda and one that I think we have some really good issues to discuss that are very timely for all of us. So, with that, thank you.

Dr. Castellanos: No, thank you, for these welcoming remarks. And we certainly appreciate you being here today and we hope that Dr. Thomas Gustafson will be joining with us, too. Dr. Ken Simon, Executive Director, Practicing Physicians Advisory Council, Center for Medicare Management will provide us with an update of the March 7th recommendation of the Council, and the Centers for Medicare and Medicaid Services' response.

Update

Dr. Simon: Good morning to members of the Council and the public. I'll review the minutes pertaining to the recommendations from the Council from the March 7th meeting. Agenda item F1, the Council recommended that CMS require vendors selected through the competitive acquisition process absorb the cost of unreturned drugs, or unusable drugs, and that vendors be willing to advance credit for drugs to patients who are not able to pay the co-pay. The MMA changed the way Medicare pays for Part B drugs to ensure that payment more accurately reflects market prices. The competitive acquisition process is the second MMA mandated change to the Part B Drug Payment system. The first change was to move to payment methodology based on average sales price, which began in January 2005. In order to meet the January 1, 2006 statutory deadline for implementing the CAP, CMS published a Notice of Proposed Rulemaking in the *Federal Register* on March 4th, 2005. We're currently accepting comments on the Proposed Rule, and those comments were accepted through April 26 of this year. All comments received were considered and included in the Final Rule that explains how the CAP will operate. At this time, since the Final Rule has not been published, we cannot respond directly to PPAC's comments because of rulemaking requirements, but we will address them in the CAP Final Regulation. PPAC's comments were received and considered in formulating the Final Rule.

Agenda Item F2. PPAC recommends that CMS requires vendors selected through the CAP be willing to provide drugs for off-label use when evidence supports such use and in those cases vendors may

use the established CMS process for determining medical necessity. As stated earlier, at this time, we cannot respond directly to PPAC's comments because of the rulemaking requirements. But we will address them in the CAP Final Regulation, which will be published shortly. PPAC's comments were received and considered in formulating the Final Rule.

Agenda Item F3. PPAC recommends that CMS allow individual practicing physicians to select on a drug by drug basis whether to purchase drugs from vendors participating in the CAP program. The CMS response: As stated, we cannot respond directly to PPAC's comments because of rulemaking requirements. But we will address those comments in the CAP Final Rule. PPAC's comments were received and considered in formulating the Final Rule.

Agenda Item F4. PPAC recommends to CMS that prices set by vendors selected through the CAP process not affect the average sales price for those who purchase drugs outside of the CAP program. As I've stated with the past two responses, we cannot respond directly to PPAC's comments because of rulemaking requirements, but we will address them in the CAP Final Rule. PPAC's comments were received and considered in formulating the Final Rule.

Agenda Item F5. PPAC recommends that CMS help affected providers find sources of affordable drugs and that CMS report to PPAC some mechanism to accomplish this goal which was recommended by the Office of Inspector General. CMS response: The issue of how to help affected providers find sources of affordable drugs is outside the scope of the CAP, therefore it was not addressed in the Notice of Proposed Rulemaking. However, CMS supports groups representing Medicare Part B drug purchasers in identifying ways in which purchasers, particularly small and rural purchasers can obtain the most favorable drug prices possible.

Agenda Item G, pertaining to the Report to Congress on contract reform. G1. PPAC recommends to CMS that any money used for incentives to Medicare administrative contractors, called MACs, be derived from new funds, or administrative savings, and not from the Physician Fee Schedule. The CMS response: Any financial incentives that are earned by MACs will be paid from the funds made available for the administration of this program, not from funds used to pay Medicare benefits. Section 911(b)1(d) of the Medicare Modernization Act mandates that CMS provide incentives for MACs to provide quality service and to promote efficiency. CMS has not yet determined exactly how incentives will be applied to the MAC

contracts, but the incentives that are established will allow contractors to earn profits, when they are more efficient, innovative, and cost effective and when they delivery better administrative service to providers and to beneficiaries. At all times, MACs will be required to adhere to Medicare law, regulations, and CMS directives, which require that claims be paid accurately and timely.

Agenda Item G2. The Council recommends that CMS continue the Carrier Advisory Committee Program. CMS response: This recommendation is currently under review by the Office of Financial Management.

Agenda Item G3. PPAC recommends that CMS maintain the accessibility of carrier medical directors offices to providers, even if that requires adding staff positions. This recommendation as well, is under review by the Office of Financial Management.

Agenda Item G4. PPAC recommends that as part of contractor reform, CMS develop more integration of Parts A and B, even if new legislation is required to allow funds to follow services from Part A to Part B. CMS response: CMS endorses greater administrative integration of Part A and Part B. And our plans for Contractor Reform are designed to achieve significantly greater integration. However, changing the source of funds for services from Part A to Part B or vice versa, is a distinct matter with broad reaching implications including on the sources of funding (payroll taxes versus premiums and general revenues). Any such change would require legislation and CMS is currently not prepared to advance such a proposal at this time.

Agenda Item G5. PPAC recommends that CMS look into combining the primary A B max, the durable medical equipment max, and the home health hospice max into a single jurisdiction in the future. CMS response: CMS agrees. While we have concluded such consolidation is not feasible immediately. We agree that it may be a desirable administrative reform. We plan to visit the separate status of DME max and Home Health max before we launch the second round of competition.

Agenda Item G6. PPAC recommends that CMS move toward more web-enabled access for provider based services to improve services at both the front end and back end. CMS response: Currently CMS has given approval for two Fee for Service contractors to conduct pilots to allow Medicare providers access to eligibility, claim status, and customer service information over a secure internet connection. The Wisconsin Physician Service, WPS, has been providing Internet service for obtaining eligibility and claims

status since August 2003 in four states. In May of 2005, the pilot will be expanded in those states, to include deductible co-insurance, and Medicare secondary payer information. Over 6900 users from the four states are currently participating in the pilot project. National Heritage Insurance Company, NHIC, is scheduled to begin internet access in May 2005 in five states. In addition to eligibility, claim status, and customer service information, NHIC will add to additional services: accounts receivable and information on the status of provider enrollment applications. When NHIC's pilot project goes live, it will include 600 providers from the states of California, Maine, Massachusetts, New Hampshire, and Vermont. CMS notified its fiscal intermediaries and carriers in March of this year of the agency's interest in approving a limited number of additional innovative proposals from contractors interested in conducting provider internet-based transactions. In calendar year 2005, CMS plans to expand the number of providers using services in the current pilots and will approve up to five additional pilot projects. Claims submissions is not in the scope of these short term provider pilot projects, but it is part of the CMS long-term strategy for future electronic services. Over the long term, CMS plans to develop a National Provider Web Portal, with a customized view of information and applications as well as a common identity management and security process.

Agenda Item G7. PPAC recommends that CMS include in MAC contracts a mechanism by which physicians can evaluate the service provided by contractors and use the results of that evaluation in determining improvement plans, or discontinuing contracts. The CMS response: As mandated by Section 911(b)3(b) of the Medicare Modernization Act, CMS will be including both provider and beneficiary satisfaction levels as performance standards for MACs. CMS will conduct a random survey of active providers to gage overall provider satisfaction with the MAC. In fact, data collection for the Medicare contractor provider satisfaction survey pilot project ended April 1st of this year. And the agency is in the process of preparing for national implementation of the survey. The results of the provider and beneficiary surveys along with the performance against other requirements will be used for the MAC oversight and contracting decisions.

Agenda Item J1, pertaining the Physician Fee Schedule Final Rule. PPAC recommends that CMS begin projecting the effect on Medicare beneficiaries' access to physician's care if the proposed decrease in the Physician Fee Schedule as a result of the sustainable growth rate comes to pass, and that CMS develop

a plan to prevent decreases in physician participation. CMS response: CMS agrees with PPAC that monitoring beneficiary access to care, given changes in physician reimbursement is a critically important issue. According to Medpak's March 2005 report, Medpak sponsored a 2004 telephone survey to obtain current access data. 88% of the responders reported that they experienced no problem, or a small problem finding a primary physician. Medicare beneficiary access to specialists was reported to be 94%. 73% of Medicare beneficiaries reported that they never experienced delays in scheduling appointments for routine care. Of the 6% of Medicare beneficiaries that thought they should have seen a doctor for a medical problem in the past year but did not, only 7% sited physician availability issues (appointment time, finding a doctor) as the principle reason. These numbers are encouraging but CMS recognizes the need to continue to work with Medpak, and other stakeholders, through out Office of the Actuary to continue to monitor this issue. Although it is difficult to accurately assess the impact on beneficiary access to physician services given a decrease in prices, CMS implemented a multi-faceted monitoring strategy that includes analyses of the number of physicians billing Medicare in a year and their corresponding average caseload. The proportion of physicians accepting Medicare assignment, the frequency of access problems reported to the 1-800-MEDICARE number and analyses of survey data on beneficiary access.

Agenda Item J2. PPAC recommends that CMS use its administrative authority to remove Medicare covered physician administrated drugs and biologics from the Physician Payment Formula, retroactive to 1996. CMS response: CMS is carefully reviewing the AMA's proposed administrative fix to remove drugs from the SGR formula, retroactively for all years from 1997 through 2004. However, this is a short-term fix, and may substantially worsen Medicare's overall financial outlook if the substantial growth in Part B utilization continues. CMS is concerned about the way Medicare reduces payments to physicians and other practitioners, whenever program expenditures for Part B services exceeds a set target, the sustainable growth rate. The SGR debate incorrectly frames physicians as part of the problem. As we think about Medicare payments, and our implementation of the vital new benefits, and our regulations and policies, the agency is committed to working together with the AMA and the many medical specialty groups to develop and implement effective, clinically valid approaches for payments that reward better quality. Pay for Performance means Medicare would pay for procedures that yield positive results by recognizing the importance of delivering quality care efficiently, effectively, and with an emphasis on

having the greatest impact on patient health at the lowest cost. However, an effective payment service in Medicare relies on physician leadership as the most essential part of the solution. And CMS intends to keep working with the Practicing Physicians Advisory Council, the American Medical Association and the rest of the medical administrations with leaders in Congress and others until we have effectively resolved this problem.

Agenda Item M. Pay for Performance Initiatives. M1. PPAC recommends that as CMS develops and implements the Pay for Performance Program, these programs should remain in alignment with certain principles and guidelines developed by the AMA and attached to the AMA written statements. CMS response: CMS is encouraged by AMA's effort to develop processes that would increase the ability to establish performance-based payment in an effective manner. As CMS develops its plans, it is carefully reviewing input from the AMA and other provider groups.

M2. PPAC recommends that CMS ensure that implementation of any quality improvement Pay for Performance Program is premised on establishment of a reliable, positive, Medicare physician payment formula. CMS response: CMS appreciates the importance physicians and other providers place on sound Medicare payments. CMS will consider this recommendation carefully as it develops plans for Pay for Performance.

Agenda Item M3. PPAC recommends that as part of the Pay for Performance Program, CMS develop criteria for electronic medical records, and data collection sets to facilitate dissemination of information technology to physician practices. CMS response: CMS is working to address issues of data collection and the adoption of health information technology. The Offices of National Health Information Technology is the lead on the department's efforts to improve the adoption of health information technology and the establishment of a certification process. CMS will work within this process to meet the intent of this recommendation.

And that concludes the responses to the recommendations provided by the Council in the March meeting, Dr. Castellanos.

Dr. Castellanos: Thank you, Dr. Simon. Are there any comments or further questions from members of the Council? Dr. McAneny.

Dr. McAneny: Yes, looking at the first one on the Competitive Bidding, on F1, actually F1 through F4, F5, and the fact that we can't really discuss this any further because we don't get any feedback is of concern to me. I'm wondering, I'd like to make a recommendation from PPAC that CMS enter an interim Final Rule to allow more comments about the CAP Program. Is that possible?

Dr. Simon: The Final Rule that will contain information pertaining to the CAP Program will be published eminently. And it's our hope and intent that at the August meeting, we'll be able to provide follow-up information pertaining to the CAP Program and enable the Council at that time to be able to provide guidance and input and recommendations pertaining to the Final Rule.

Dr. McAneny: There won't be an interim where other people get to make comments as well?

Dr. Simon: Well, there'll be a 60-day comment period, so that those comments will be—

Mr. Kuhn: Well, I think what we're—right now, we're moving to publish a Final Regulation. And you're asking us not to publish a Final Regulation but an interim Final so there can be a second round of questions. I think that's a recommendation that PPAC can make and we can take it under advisement. But I can't make a commitment right now. That's what the agency's got to do. But later today I think that would be a recommendation you could make.

Dr. Castellanos: Are there any other comments? The only question I have is that under G2 and G3, you mentioned these were under review by the Office of Financial Management. Both of these issues are very important. The CAC and the accessibility to CMD to the practicing physician. And are we going to be able to get information back on that or do we have to resubmit these as recommendations? These were the G2 and G3 and you mentioned they were under review by the Office of Financial Management.

Dr. Simon: I will provide follow-up to the Council once we've received the recommendation from the Office of Financial Management.

Dr. Castellanos: So this will be published in the next meeting and we'll have it as a recommendation?

Dr. Simon: When those recommendations are available, we will provide follow-up.

Dr. Castellanos: OK, and this, I think is just a typographical. On J2, you mentioned that CMS is carefully reviewing the AMA proposal. I think this was a PPAC proposal, wasn't it? This was our recommendation to propose the administrative fix?

Mr. Kuhn: I think the issue there is that the AMA had made a recommendation back last year that this occurred, and to our General Counsel, but you're referencing specifically had also made a similar recommendation.

Dr. Castellanos: Yes, J2 was our recommendation and you answered it by saying it was an AMA proposal. It may have been an AMA proposal, but it was our recommendation at this meeting.

Dr. McAneny: I have a question on the Js as well. Looking at this data, obviously data can be looked at either way from the 80% could or the 12% couldn't find a primary physician, or 73% of Medicare beneficiaries could never experienced delays, which means 27%, more than a quarter, did. So my question would be what would CMS take, what percentage of difficulty of a beneficiary finding a primary or a specialist physician would CMS take as a red flag that problems were imminent? What sort of marker would raise your concern about that?

Mr. Kuhn: I don't know if we've set a threshold yet or not, you know. It's kind of a something we'd like to look at some of the trend analysis here and see and kind of connect all the dots and see kind of all the trends we've seen, and then talk to the various researchers we have in the agency and determine what are some of the thresholds in terms of a fall-off that some people would look at critical. Also, we'd like to sit down with Medpak as well, because they've collected a lot of good information here and consult with them at the same time. So it's something that we're looking into but I don't think we've set a specific threshold just yet.

Dr. Castellanos: I think just to answer the question, the trends are important. But I think what you're going to see if you ask most of the practicing physicians on this council, is that people are not dropping out of taking Medicare patients, but delaying seeing them, not letting them into the practices as often as they would like. And it's really delaying being seen. When you're talking about over a quarter of—how many Medicare participants do we have? How many million?

Mr. Kuhn: Probably about 43 million.

Dr. Castellanos: So you're talking over 10 million people having problems getting in to see a doctor. I think that's a significant problem.

Dr. McAneny: You can call me Barbara. As a follow-up to that, I'm wondering you know, when I tell patients who are complaining to me to call 1-800-MEDICARE, I get this look like you must be kidding

from the patient. Because it's not exactly a responsive phone call often. And I'm concerned that as you look at these broad pictures of the percentage of people who report having difficulty that you may be missing something that you might find in various subsets; that perhaps it may not be a broad indicator will tell you much until really there are significant trouble spots in the system. So I'm wonder if CMS is doing any specific sort of subset research on things that you think may be issues? Are people having difficulty accessing general surgery with the decreasing number of general surgeons? I'm concerned about whether or not people will be able to access incident to drugs with the changes in their—it may not be the broad ability of people to get their anti-hypertension checked, but there may be some canaries in this mine that we should be looking at so that we can see whether or not access is going to be a problem before there is a generalized problem.

Dr. Castellanos: Dr. Leggett, it's good to see you. Did you have a question?

Dr. Leggett: Thanks, Ron. I was just going to sort of tag along on Barbara's point. Frankly I think CMS didn't even answer the question. I mean the question was really address the issue of physician reimbursement as it related to the SGR, and what CMS basically said was we don't have a problem with our patients being seen, therefore the physician assessment question in our mind is not relevant. That's my read on this information and I guess my question becomes, how far do you wait for the drop off, and there's this idea that there is a value for service that irrespective of beneficiary access. And whether or not you drop or undervalue your service so low, irrespective of the access question, the question becomes what is the service worth? And how low do you go on the reimbursement on that? And I think that part of the issue becomes access, it becomes service, and the third prong in this is SGR related. And frankly, it seems like when I read your response, the response to me basically says, pretty much that's your problem. We don't have a problem with our patients being seen. And we just need to move on.

Dr. Castellanos: Dr. Powers?

Dr. Powers: We keep going back to the Medpak data and I think Medpak may have gone about that, it's nice data, but it's not necessarily reflective with what is potentially happening. And if you look at the percentages of people going into primary care these days, I think we have a problem. And I think there are positive reasons for going to primary care, and negative reasons whatever, but the numbers are going down. And the internal medicine may be staying the same, but these people are going into specialties. So

that's not reflective. People going into the nonprocedural specialties. All of that is going down and I think they're the people that are going to be hurt first by these declines because they've taken what they can take so far. But the future is grim because people aren't even going into primary care specialties.

Dr. Hamilton: I agree with what Dr. Leggett said. I really think that the answer does not directly relate to the question that was asked. The question projected into the future of what would be the effects of something on the future access. The answer related to past access. I just don't think the two are comparable. I think that it certainly, the methodology of these figures would be something of great interest, because they are not in keeping with most of our personal experiences. Especially for Medicare beneficiaries that are older and have had a primary care physician, which then went out of practice, and to try to reestablish with a new primary care physician when one is 75 or 80 years old, is a very difficult thing for many people. And I just get many patients calling much higher percentage than I would expect these figures relate.

Dr. Castellanos: Are there any other comments? Please.

Dr. Leggett: I just have one additional. It was under J2 in your response as it relates to this notion that we can pay for performance. That response is probably the most convoluted thing that I've read in recent months. Pay for Performance means Medicare would pay for procedures that yield positive results by recognizing the importance of delivering quality care efficiently, effectively, with an emphasis on having the greatest impact of patient care at the lowest cost. I mean, what does that mean? Basically what you're saying is we'll kind of look at the landscape of physicians. We'll decide which doctors are delivering care effectively and efficiently. My question is where are you going to get the scale from? Who's going to enforce it, who's going to let you know which doctors are above or below it? And then how are you going to decide to performance-based pay them versus what you're paying everybody else? It just seems circular for lack of a better word, and quite frankly not something that you can implement.

Dr. Castellanos: Thank you. Are there any other comments? Are there any recommendations by the Council? Dr. McAneny.

Dr. McAneny: The first one is that PPAC recommends that CMS issue an interim Final Rule to allow more comments about the CAP program.

Dr. Hamilton: Second.

Dr. Castellanos: Is there any discussion on that? Seeing none, all in favor?

[Ays]

Dr. Castellanos: Opposed? The second?

Dr. McAneny: And the second one is that PPAC recommends that CMS develop a plan to monitor critical subsets or indicators of beneficiary access as an early warning plan to determine problems in the system and to develop a plan to address possible declines in access. So it's a plan to monitor and then a plan to address if you find a problem.

Dr. Castellanos: Just a question. In you comments, you mentioned by specialty. Is this by specialty or just in general?

Dr. McAneny: Well, I think there's a variety of indicators that could be, and maybe the first people who are going to have trouble are the people without a Medigap coverage, or the Medicare and Medicaid dual eligibles. Because in my experience, in my state, where that's 20% of our Medicare population, those folks really have a difficult time accessing care, particularly expensive care. They can usually find a physician who's willing to donate their time for free, but once they need a test or a procedure or something more invasive done, they have a hard time accessing it. So that might be an indicator. It may be specific specialties. If you look at specialties that are in short supply. Those may be the specialties that will be the first indicator that there's a problem in access for patients. So rather than having these big broad numbers that could fool us for a long time until it comes crashing down among our ears, I'd like to have CMS spend some time looking for what the suspect will be those first things to fall, the canaries in the mine that will really give an early warning system, and give us some time to fix this back up. Us being the country.

Dr. Castellanos: Can you read that one more time?

Dr. McAneny: Not the whole soliloquy but just the—

Dr. Hamilton: [off mike] It ought to be new Medicare patients versus previously established Medicare patients.

Dr. Castellanos: Can we incorporate that?

Dr. Hamilton: Which I think incorporates a major difference.

Dr. McAneny: And those with and without Medigaps or duel eligibles?

Dr. Castellanos: Can we incorporate that into your…

Dr. McAneny: Critical subsets or indicators such as new Medicare patients or those without Medigaps. And what was your third one?

Dr. Hamilton: Specialty versus primary care. Age of Medicare beneficiary, i.e., new versus established patients seeking the primary care doctor.

Dr. McAneny: OK, so new versus established—

Dr. Hamilton: Previously established patients, seeking new—

Dr. McAneny: So not people who just were 64 and were on insurance X and then became Medicare, but somebody who moves to your town, they're 75 years old—

Dr. Hamilton: Somebody who is 75 who's doctor retires and now tries to find a new primary care doctor.

Dr. McAneny: Right. So..

Dr. Castellanos: Can you read that recommendation one more time?

Dr. McAneny: Me, or Dana?

Dr. Castellanos: I guess you, then Dana.

Dr. McAneny: PPAC recommends that CMS develop a plan to monitor critical subsets or indicators such as new versus established Medicare patients, those without Medigaps, or specialty versus primary care access and as an early warning plan, I guess we can just delete that. Specialty versus primary care, and develop a plan to address possible declines in access before it becomes widespread. I modified that a little bit.

Dr. Castellanos: Is there any discussion on that recommendation? Seeing none, all in favor?

[Ays]

Dr. Castellanos: Opposed? Thank you. Are there any other recommendations by the Council? At this time, Mr. Robert Bennett, the Deputy Director for the Physicians Regulatory Issues Team, Centers for Medicare and Medicaid Services will provide us with an update on the Physicians Regulatory Issues Team, better known as PRIT. In his presentation, Mr. Bennett who has worked for PRIT for almost 2 years now, and has worked for CMS for almost four years, will discuss a number of important issues that the Physicians Regulatory Team is tasked with and their ongoing effort to reduce the regulatory burden on physicians who participate in the Medicare Program. The Director, Dr. William Rogers, normally gives the

PRIT report at our quarterly meetings, but had a previous confirmed speaking engagement today at the American Urology Association Meeting in San Antonio. Mr. Bennett.

PRIT Update

Dr. Bennett: Thank you. It's an honor and a thrill to present at the PPAC. I've sat in on 15 of the meetings so it's quite a treat for me to be up here today. Dr. Rogers did ask me to apologize to the Council members for not being here. But he had accepted an engagement before this date was set for PPAC. I'm here to give the PRIT report.

I will give an update on our current issues, and them make sure all of the Council members have our contact information. All of these issues are on our website if people are having a hard time reading them. The first issue is about reporting payers who are non-compliant with HIPAA transaction and code sets, during one of Dr. Rogers's speeches, a provider asked how to anonymously report payers who aren't HIPAA compliant. We checked into this at the CMS Office of HIPAA standards on a way to do this. We've put this issue on line because some providers didn't know if they could report potential violations anonymously. The clarifying the rules concerning volunteer graduate medical education. Dr. Rogers and I have been in touch with the American Osteopathic Association, and have asked them to provide specific examples of situations not covered by our recently released volunteer teaching physicians Q&As. They have promised that to us in the next few weeks. The critical care bundled service issues—two carriers are currently reviewing claims for intubations and other critical care services for patients who go to the operating room. This review is triggered by the global period of the surgical procedure that the patient undergoes. We don't feel that this is necessary to review these cases. Therefore, we are working to send these carriers a joint signature memorandum to that effect. RVUs for pediatric codes. The American Academy of Pediatrics would like CMS to publish in the Physician Fee Schedule RVUs values for services not covered by Medicare. When the comment period opens for the 2006 Rule, we will assist the AAP to make sure their comments are addressed. The E&M half-level payment issue. A Kansas City physician billed a level three service, and surprised when the claim was paid at a level midway between 2 and 3. What the carrier did was to process the claim as a 99499, which is the unlisted E&M-Code, which gave the carrier the authority to price it. CMS policy experts determined that this was permissible, though labor intensive for the carrier. CMS has instructed the carrier to create. CMS has instructed the carrier to create

educational materials for providers to explain this. ASP Problems. Congress wrote the statute which created ASP. Implementation has been a real challenge. The PRIT receives one to two emails a week from physician groups that aren't able to meet costs at ASP plus 6. We then send this info to a CMS ASP Task Force that examine the pricing data sent by the physician groups. We are very aware of the huge economic challenges this represents for many practices. The NPI, which starts today. Happy NPI Day. [laughter] Today, Ms. Brandt will provide more expert testimony on the NPI process. But the PRIT remains available to any providers who encounter problems with this process. The Chemotherapy Push Issue. A recent definition of an IV Push was any infusion of less than one half-hour. Because the requirement that a health care professional be in constant attendance, this definition provokes some complaints from the provider community. The CPT Editorial Committee met in February and redefined that an IV Push is now infusion of less than 15 minutes. This makes the requirement of a health care professional in constant attendance less burdensome. A MedLearn Matters article is available for provider education, and the link to that article is also available on our PRIT webpage. When is it appropriate for Medicare to bill for first assistant? We've put a link on our website to the manual that contains the rules for when a second assistant can be paid in a teaching hospital. The link is right there that explains all of that in detail. Recovery Audit Contracts. Mr. Polansky will be discussing that, so I'll leave that to him. Competitive Acquisition Programs. That's also discussed by Don Thompson, who's the expert on the CAP Program. The co-signature requirement in a [CAH?]. The Interpretive Guidelines were recently changed to require that 100% of physician-assistant outpatient charts be signed by the supervising physician and those Interpretive Guidelines were re-examined, saying that 25% of a critical access hospital physician assistant charts needed to be signed, could be signed by physician assistance. The order of power-operated vehicles issues. The national coverage determination was released May 5th, but we still haven't released the regulation yet which will say what specialties can prescribe power-operated vehicles. The Cardiac Rehab Issue has been with the PRIT for some time. There is an Office of Inspector General Report that's in final clearance, and hopefully will be released in the next couple of weeks. CMS can't issue any policy changes until that OIG report is released. The Security of Anesthesia Carts. Proposed Rule, which satisfies the anesthesiologists, has been released, and we expect it to become the Final Rule in its current form. The history and physicals by podiatrists. Also a proposed rule which satisfies the podiatrists has been released, and we expect it to become a Final Rule in

its current form. States and hospitals now have the authority to determine what specialties can perform history and physicals. The outpatient mental health treatment limitation. We've been told in the last Open Door Forum that this policy is soon to be released. The Macro Issue. CMS has received language from the American Association of Medical Colleges. This is language the AAMC is comfortable with, describing appropriate use of Macros in teaching documentation. And we have helped submit that language to CMS Program experts for clearance. The post anesthesia reports issue. A proposed hospitals Conditions of Participation address this issue. Now the post-anesthesia assessment in writing, the post-anesthesia report can be delegated to practitioners who are qualified to administer anesthesia. The last one, the verbal orders issue. This is also in the Propose Hospital COP. This proposed provision states that all patient record entries must be legible, complete, dated, time, and authenticated in written or electronic form, by whomever is responsible for providing or evaluating a service.

Dr. Castellanos: Thank you, Mr. Bennett for that update, and for your presentation that PRIT continues to tackle a wide variety of issues that impact the practicing physician. We certainly appreciate your efforts and those of Dr. Rogers. Are there any questions or comments from the Council members?

Dr. Senagore: Two actually. When will that terminology on the piece of Macros be available?

Dr. Bennett: Dr. Simon has been also working on this. He might know the timing better than I.

Dr. Simon: That's actually a process that's under review. We've been working with the AAMC over the past few months regarding it, and I think that one of the concerns for all involved is that there are a variety of electronic healthcare systems out there that have a varying degree of sophistication. And one of the, and I think both AAMC and CMS both share the same view that we want to safeguard physicians from the prospect of using an immature system where upon an audit review, it doesn't reflect the tailoring of care that's been provided by the physician to the patient. To that end, we have been monitoring closely over the past year the technology to see when the majority of systems reach a point of sophistication where one may be able to safely use a macro system without perhaps having to provide additional written input into the medical record. We envision probably meeting with AAMC over the next couple weeks as we continue to refine the guidelines as it pertains to macros and I would probably suggest that over the next few months, you'll be able to see the common ground that AAMC and CMS have established in regard to changing the guidelines for Macros.

Dr. Senagore: Follow-up question to the guidelines for timing and dating. If you have an electronic medical record system, then it becomes easy because everything is time-stamped. But it seems that that regulation is somewhat onerous for clinics that are set up on a hospital campus to have to time every clinic office note and every clinic H&P, I think is beyond the expectation of the timing and dating of inpatient and surgical procedures that are done on an ambulatory basis. So if we could get some kind of exclusion for having to time stamp every one of those clinic type notes I'm not sure what the terminology would look like for that, but if we could work that into the regulation, that would be helpful.

Dr. Simon: I think if that's a recommendation from the Council then that would figure into the consideration as well.

Dr. Castellanos: We'll make that as a recommendation, then. Dr. Hamilton.

Dr. Hamilton: I wanted to ask a question to clarify in my own mind the second item clarifying the rules concerning volunteer graduate medical education. The issue there, I'm not sure whether this was a typographical mistake or maybe I just don't understand the problem. It says teaching physicians feel that the rules concerning the use of volunteer facilities are unclear. I think that ought to be volunteer faculty members?

Dr. Bennett: Yes, sir. Thank you.

Dr. Hamilton: Because the issue really isn't what's the location, it's with who's doing the service. And I don't know if you've had any trouble getting examples of this, but I can site you one very brief one, and that is that more and more academic medical centers are contracting with federally qualified health centers to provide primary care services, and to use those facilities are part of their teaching programs. When they do this, the FQHC bills and collects for Medicare for the professional services in appropriate cases, or Medicaid. And when there are volunteer physicians that fill in those spots from time to time, there have been some questions as to whether or not the FQHC is able to collect for their professional services. And this is an issue that needs to be resolved. Because when you have doctors that are willing to contribute their time to teach medical students and residents for nothing, and the FQHC is compensating the academic medical center for providing this service, there's no reason why the FQHC shouldn't get paid for that effort. And this is a situation that probably wouldn't come up very often, but it is a very significant issue in

using volunteer physicians who wish to donate their time to the medical school when they are performing that volunteer service in an FQHC. So that's an issue that could be easily resolved.

Dr. Simon: In your experience, are they currently, the FQHCs are currently not able to be reimbursed?

Dr. Hamilton: There have been some concerns about it. I can't site you how many examples there are but they're very concerned about that because when the academic medical centers will contract to provide a, say pediatrician or an internist, or a family practice doc slot, and then periodically that doctor may be on vacation or on a meeting or something and they may fill in with a volunteer doctor, there's a question as to whether or not the FQHC can bill for that doctor's services, and they certainly should be able to. And it shouldn't be a big problem. But it apparently comes up.

Dr. Simon: Well that's something that perhaps we can work with you on, because it may relate to the legal construct of how the legal construct of the relationship that exists between the academic medical center and FQHC. But I think it would be worthwhile for us to explore it to see if we could develop a common denominator.

Dr. Hamilton: Applying some language for these contracts to be developed that would accommodate this concern.

Dr. Simon: That's correct.

Dr. Hamilton: But that should be faculties instead of facilities.

Dr. Castellanos: Are there any other comments? Dr. McAneny?

Dr. McAneny: I'd like more information please about the Evaluation and Management half-level payments. It's from the little I know about it and what you just said, it sounds as if the physician is figuring that they're documenting at a given level, billing at that level, and that the carrier is then deciding that the documentation is insufficient etc., and down coding a bit. Now isn't this very similar to the lawsuit that just occurred in New York and a couple other states where they sued some private carriers for bundling and down coding and won those suits? So this is sort of an alarming process.

Dr. Bennett: I'm actually not familiar with the New York lawsuit. But this is the way you described it; a bit of exactly how you described it. They're billing at a level three and then getting paid basically at two and a half. And the physician that approached us on this was very reluctant to because he

would rather get paid at a two and a half than a two, but the carrier did not believe that they had documentation to be paid at a three.

Dr. Castellanos: Dr. Senagore?

Dr. Senagore: To follow up on that. Even though the RUC and PEAC have struggled for many years to try to come up with how much documentation you need for certain levels, it still that 5 levels apparently exist. I think the issue is two-fold. Did that individual truly not meet the minimum guidelines or not? And I think that's probably debatable. But once you meet a certain threshold then it should be the levels [off mike]. I think this is a scary slope because now how do they decide it's not 2 and a quarter, 2 and three-quarters, 2 and five-eighths. I mean it becomes very capricious then that they're creating their own fee schedule, based on very poor data and no way to defend yourself in an audit in terms of whether it should be two and a half or some other percentage.

Dr. Castellanos: Are there any other comments? I have one on ASP. My understanding is that PRIT is maintaining a list of what we call these problem drugs and there are about 40 of these that you have collected today. I've looked at them and I don't see any list of them as such. I know you mentioned both March 10th and April 8th that you've got this—this is on the PRIT issue. I'm hoping that this list will be available so that we can look at it, to make sure that some of the drugs that I use are perhaps on that list.

Dr. Bennett: We've really been working with CMM's group that is responsible for the ASP list and just been helping to get them the data for that. They have the list.

Dr. Castellanos: Do we have any recommendations to PRIT at this time? Dr. McAneny?

Dr. McAneny: PPAC recommends that CMS and its carriers use the existing documentation guidelines for payment levels, rather than arbitrarily assigning other payments.

Dr. Castellanos: Is there any discussion on that? Dr. Urata?

Dr. Urata: Did you say that there's a way that the insurance companies, or the intermediaries can do this? They used a code 99 something or other that you mentioned, and that gave them legal ability to do this? I guess I've got to learn a little bit more about this 99 something or other.

Dr. Senagore: No they just move it to an unlisted code. I mean that is a scary thing, too, that they can change the whole documentation and code submission by their own volition.

Dr. Urata: Why don't they just send it back to the physician and say recode this? Why are they doing it themselves? And say this is what you get.

Dr. Simon: I perhaps will have an opportunity at the next meeting when Dr. Rogers is here to perhaps give us information pertaining to this particular case, where it will shed more light on it. Because I don't think there's probably enough information available this morning for us to have a cogent discussion on it.

Dr. Castellanos: Can we make that as a recommendation that PRIT will come back to us at our August 22nd meeting with more detailed information? All in favor?

[Ays]

Dr. Castellanos: Opposed? Are there any other recommendations?

Ms. Trevas: [off mike, requesting clarification]

Dr. Castellanos: That PRIT come back to us—

Dr. McAneny: I'm still a little concerned with the idea of just sort of throwing out the E&M coding system that we've currently been using and saying, well, it's OK, we'll just assign you a code and that's what you get and that's how it works, because even if this is just one case, that could be the thing that throws the system then into chaos because it's one case this time, and 10 cases by August, and you know, a million cases next year. So I would like to combine that, yours that they come back with more information next time, and that we continue to recommend that CMS use the existing documentation guidelines for payment levels, rather than arbitrarily assigning other payments or codes.

Dr. Castellanos: Will you accept that?

Dr. Simon: Yes.

Dr. Castellanos: No, Dr. Urata, will you accept that as an addition to your recommendation?

Dr. Urata: I didn't realize I recommended—

Dr. Castellanos: OK, Barbara excuse me [laughter].

Dr. McAneny: Will you accept it?

Dr. Castellanos: Yes, I'll accept it. [laughter] I thought I was just emulating your suggestion, I apologize. Can we read that one more time. Dana you're the one. You need to read it.

Ms. Trevas: PPAC requests that PRIT provide more detailed information at the August meeting on the issue of carriers half-level payments, and PPAC further recommends that CMS and carriers use existing documentation guidelines for payment levels, rather than arbitrarily assigning other payment levels.

Dr. Castellanos: Is there any further discussion on that? All in favor?

[Ays]

Dr. Castellanos: Opposed. I'd like to make one recommendation that PPAC recommends that PRIT come back with a list of these 40 problem drugs that being collected under the ASP problem list. Is there a second to that?

[Seconds]

Dr. Castellanos: Any discussion? All in favor?

[Ays]

Dr. Castellanos: Opposed? Are there any other recommendations? Dr. Senagore?

Dr. Senagore: PPAC recommends that PRIT evaluate the proposed rule for hospital COP and seek to exclude non Emergency Room E&M visits from the need for time stamps.

Dr. Castellanos: Is there any discussion that? All in favor?

[Ays]

Dr. Castellanos: Opposed? Are there any other recommendations? OK. Being a urologist, I have a very special understanding and empathy for frequent and time-honored break. So we're going to take a break now and we'll report back maybe around 10 minutes to 10. We'll try to keep on schedule.

Break

Dr. Castellanos: Maybe we could sit down and see if we could get started again. Our next discussion is going to be on Recovery Audits. We'll continue this presentation with Dr. Jesse Polansky who is a Public Health Physician, and Melanie Combs. Melanie it's been a good while since we last saw you. She tells me she's been with this program for about sixteen years, and we certainly appreciate seeing you again and looking forward to both you and Dr. Polansky's presentation. Dr. Polansky is the medical director for the Program Integrity Group in the Office of Financial Management in the Centers for Medicare and Medicaid Services. As we said, he's a preventive medicine physician in public health, who, prior to joining Medicare Program, worked in a variety of leadership positions, both in the pharmaceutical

industry and in the managed care sectors. Dr. Polansky will provide us with information in the current status of the Recovery Audit Contract Initiative. This effort is aimed at providing an effective, yet cost-effective means to ensure adequate payments to providers. We welcome both Dr. Polansky and Melanie Combs.

Recovery Audits

Dr. Polansky: Good morning. We're going to try to keep things fresh by splitting the presentation in half so you won't hear the monotony of my voice throughout the presentation. We're somewhat warmed up. We sent the latter part of last week in New York State, talking to providers about the Recovery Audit Contractors, and had a fairly seamless time. We were welcomed and treated pretty graciously and we would expect nothing less from this esteemed group today. Though your reputation does precede you. [laughter] We're looking forward to providing you with a fair amount of detail and I'm very lucky to have Melanie Combs here, who has enormous experience, even beyond the scope of the RAC Program, which is why we thought it was essential she was here as sort of the pivotal player in the CERT program and a tremendous amount of experience in the general operations of medical review. So the Recovery Audit Contractors is a very new beast. It was created through the Medicare Modernization Act. It's Section 306. And it's a demonstration project, meaning it has a 3-year lifespan. And the purpose of this is to evaluate the savings to the Medicare Program, when Recovery Audit Contractors are used to identify underpayments and recover overpayments. It's important to say the focus of this is not fraud. In fact, if it is fraud, as you'll see later on, that's actually handled through other mechanisms. The focus here is on errors and trying to identify and correct those, which is in the best interest of providers and the program itself. There are two distinct types of Recovery Audit Contractors. One is claims review and the other is Medicare as secondary payer, or the acronym MSP. It's essential to understand three points. One is the RACs will not conduct prepayment reviews. And the RACs will not be looking at activities related to E&M-codes, as we all understand that's a very complex ambiguous territory, and what we want to do in the RAC Program is really deal with issues that are considerably more black and white. So this is actually migrated even from the slide that it's really off the table, except for global surgical payments. Anything you want to add to that, because that's such an important point. The RACs will perform identification recovery functions for services with claims pay dates in the prior three years. So it's a program that has a fair amount of duration

in terms of looking at past claims. And the prepayment process will not change for Medicare providers. So this is business as usual, which is something we'll emphasize throughout the day. The contractors are obligated to use all the policies and procedures present in the Medicare Program, whether that's LCDs, NCDs, coding rules, payment rules, etc. Now in terms of identifying MSP occurrences, they'll only identify situations where another employer or insurer should have paid the claims. The RACs will not be in the business of identifying situations involving workers compensation, automobile cases, liability cases, VA benefits, and things like federal [blackbone?] benefits. There are five Recovery Audit Contractors and they'll be covering the three states where the program is underway. That is California, New York, and Florida. According to the statute, we were obligated to do at least two states but in terms of the volume of claims and the dollars of claims, there was a much cleaner break after identifying the top three, because there was a pretty big drop off. So we went slightly beyond the statute, but we felt we had very strong rationale. All three states will have RACs who will conduct claims reviews, but only in California and Florida will the RACs be doing Medicare secondary payer reviews. Does everyone know what an MSP is? Is that worth clarifying for some? It's Medicare as a secondary provider. So this is the situation, secondary payer, thank you. So this is the situation in fact, instead of Medicare being primary, it was an alternative insurer. So there's an ability for us to go back and redistribute who's actually paying that claim and recover some dollars. OK. To give people a sense of who the contractors are in the three states; in California, it's something called PRG Schultz international, Florida, it's Health Data Insights, New York, it's Connelly Consulting. These were put out to bid. It was a competitive bidding process. There was a fair amount of interest and these were all the finalists. And I actually spent the past two working days with Connelly Consulting. It's important to note that they have been working actively with providers through their commercial business contracts. So these are not new kinds of contractors, or new kinds of enterprises and in fact, the provider community, at least in New York, were fairly familiar with actually Connelly in their business processes. But what Connelly did say with great clarity is they are making the transition to the Medicare rules, because this is not commercial business. This is the Medicare Program, which is highly defined and highly orchestrated. I'm going to turn this over to Mel.

Ms. Combs: The next slide shows us the two MSP contractors. Again, there's one in California, Diversified Election Services, and in Florida is Public Consulting Group and like Dr. Polansky said a

moment ago, we do not have an MSP RAC in the state of New York. So what iis it that the RACs are going to be doing? Well according to the statute, they will be identifying Medicare underpayments and overpayments and they will be recouping overpayments. And they're going to be doing this using their software that analyzes the data, and lets them figure out where these overpayments and underpayments are, and they have already been given the data. They got the data several weeks ago, and they're busy crunching it through all their algorithms and computer software now. They will also be using complex medical review, that's the word that we use for when you order up the medical record from the doctor or the hospital and you review the medical record. And they have the option of either going on site to the provider's location to look at those medical records, or do it the traditional way of sending a letter, asking the provider to send a copy of the medical record. They can do it either way. When they are dealing with inpatient hospital settings, they will be paying for the medical records, just like the QIOs do today. When they are dealing with physician claims or outpatient hospital claims, or DME claims, they will not be paying for the medical records, just like happens today, with the carriers, the FIs and the DMERCs. And let me just emphasize they will be using clinicians to do any kind of medical record review. It's the same standard that we have for the carriers, the FIs, and the DMERCs. They must be using at least an RN level person to review the medical records. Providers will have the right to discuss issues with the Recovery Audit Contractor. Anybody that gets a letter asking for a medical record, or a demand letter, asking for money, can call the RAC up and the RAC has to have somebody there that can answer their questions. The provider will also have the normal administrative appeal rights that they have always had. For physicians, for outpatient hospitals, for DME, for everything except inpatient, the appeal process will be exactly the same. There will probably be a slight change on the inpatient hospital side, in terms of where the appeal gets filed. They probably will be filing their appeal with the fiscal intermediary instead of a QIO. But the rights remain the same. Second level of appeals will be conducted by qualified independent contractors. We now call them QICs. And the third level will be conducted through ALJs. So everything stays the same in the appeal process, with the exception of that first level of inpatient hospitals, where it will be filed in a different place, but the rights remain the same. The question is, is there a financial incentive for the RACs to identify large numbers of overpayments? And I think our reaction to that, our response to that is that there is an incentive to identify valid overpayments. It's important for the provider community to

understand that the RAC will not get a contingency payment if the appeal does not hold up at the first level appeal. They will only be making a profit if they find valid overpayments that can hold up during the appeal process. And the RAC is required to defend its decisions through the entire appeal process. Internal controls. This is a really important one to me. CMS will be establishing an internal control function to make sure that the decisions that the RAC is making are accurate claims decisions. We are in the process of hiring an evaluation contractor who is going to help us submit a report to Congress, not later than 6 months after the end of the demonstration. And we are going to be using this evaluation contractor to help us look at a number of things. I'm sure we'll be looking at savings. I'm sure that's the obvious thing, but we're also going to be trying to evaluate the impact on the provider community. Sort of the hassle factor angle on this. We'll also be looking at including on this report to Congress the outcome on those internal controls. How accurate were these guys at making decisions? So those are the kinds of things that we'll be putting in our report to Congress. I'm sure we'll also include not only the savings to the trust fund that has come from this program, but also the additional cost. How many more appeals did we have to go through? How burdensome, how costly was this program to operate administratively? And there's the email address if you have any comments. We do post them to a Frequently Asked Questions site, but we can send individual responses if you just drop us an email. And I guess at this point we'd like to open it up to any questions that you all might have.

Dr. Polansky: Our intent was to make sure we left a fair amount of time for questions, because we suspect there will be quite a few, and if they're things we can't answer, from what I understand, your protocol is to bundle up the questions and send them to us and then we can sort of respond accordingly.

Dr. Castellanos: Dr. Polansky and Melanie, we certainly appreciate this very informative presentation. Do members of the Council have any questions they would like to ask?

Dr. McAneny: I was talking to some of the folks from New York who met with Connelly and one of the concerns that I heard there that while Connelly was planning on looking at inpatient evaluations and inpatient procedures, they were also talking about how in that setting they were looking at E&M-codes. Well, this was very perplexing because E&M-codes for physicians by definition are Part B, not Part A. So are the contractors really clear on the RAC contractors really clear on the fact that an E&M-code from a hospital is a part B and not a Part A?

Ms. Combs: Let me try to take that one. There's sort of two parts in your question there. The first part that I want to address is that this particularly recovery contractor said they were going to be looking at inpatient services. We have set up as a requirement of this contract that each one of the recovery audit contractors that are working on claims issues; so the three claims RACs, they have to submit to CMS a list of the claim types that they're going to be focusing on. And each one of the three has submitted a list, and it's a list of one. It's one claim type that each one of them are going to be focused on initially. And that is inpatient hospital services. So for all three states, the claims RACs are going to be starting by looking at inpatient hospital services. I don't know how long they're going to stay on inpatient before they move to another claim type, but before they do, they would come to CMS and say, we're not ready to move on to ambulance services, or DME services or whatever it is that they're going to be looking for. The E&M services that they will be looking at, that RACs are allowed to look at, according to the statement of work the way it's written today, is for global surgical. In other words, if a physician bills for an E&M service, within the global surgical period, and they should not have—it's within the 90 days or it's within the 30 days or whatever those rules are. That is something that the recovery audit contractors are allowed to look at. They are allowed to identify those situations. They are allowed to recoup any overpayments that they find there. What they are not allowed to do, what's off the table, is looking at E&M services for correct coding, the levels of services, they billed a level 3 and they should have billed a level two, or as we heard this morning, they billed a level 3 and they should have billed a 2 and a half! So those are the kinds of things that for now are off the table. CMS again, is looking at the AMA Resolution 819 that suggests deferring to the physician's judgment in one level differences, and until we get completely done evaluating that particular recommendation, we don't want to have the RACs start looking at E&M services for correct coding issues, for level of service issues, but they are still allowed to look for global surgical issues and my guess is that's what Connelly was talking about to those physicians that you were speaking with, Dr. McAneny.

Dr. Polansky: Let me just emphasize one thing Melanie said. The context of what the recovery audit contractors are focusing on is something very important to us. We want to be able to alert the provider community where the RACs are headed so they can prepare both in terms of work load, etc. So though the preliminary sense from the contractors is that they want to focus on inpatient claims, they're in the process

of doing this elaborate analysis of this large volume of claims. It is possible that their orientation shifts. It's unlikely. But once they're done with their analysis, they'll come back to us and say, yes, we're going to be forging ahead with inpatient claims, or perhaps we're migrating in another area, which is unlikely. But that is one thing that we're very committed to and that's informing people in advance the direction in which the contractors are headed.

Dr. Senagore: Couple questions. Is this focused primarily then on CPT-coding issues or DRG, so Part B or Part A, or both?

Ms. Combs: Both. Anything is on the table. Except cost report audits are off the table. But any kind of claim, DRG, coding coverage, billing, any of that kind of stuff.

Dr. Senagore: OK, I guess it seems to me, and you might have data that suggests otherwise, but by the time it gets through my screening software, and CCI and your software, it's hard to understand how many overpayment CPT-codes there are, barring the fact that simply I describe a different operation than I coded for, which is a different issue, as you alluded to earlier.

Ms. Combs: We know from the improper payment report that comes out every November, that there are about 10.1% of the dollars that are paid in error. And so it's that piece of the pie that Congress is looking at when they say there are overpayments out there. 10% of the claims, the dollars, that are going out of this Fee-for-service Program, are being paid in error. And those are errors in both directions, but the majority of them are overpayments and so it's that piece of the pie that the recovery audit contractors are going to be looking for.

Dr. Senagore: Then, second question on the MSPs. Oftentimes, that's confusion on the part of the beneficiary, not know exactly who their insurer is and who their card is. Will there be information relating back to the provider then, to alert them that they have incorrect information in their system in terms of demographic data.

Ms. Combs: I don't know the answer to that one, do you?

Dr. Senagore: Because that's most typically the reason, is the patient doesn't recognize the Medicare is secondary.

Ms. Combs: The word that I have heard, and I'm not an MSP expert, is that on the MSP side, it will be almost invisible to the provider. The physician. So I'm not sure about that final piece of once they get—

Dr. Senagore: There's a reclamation of dollars, then, because Medicare should not have been the primary payer, then something should be relating back to the provider to say this is why you have an error in your claims submission data, and you need to upgrade that patient.

Dr. Polansky: Yeah, but as Mel said, though, it's supposed to be seamless to the provider. Any—

Dr. Senagore: Well, you'll take money back for that, right?

Dr. Polansky: But from the other insurer. There's not going to be any contact. But the issue of perhaps channeling information to let them know is something we can right back.

Dr. Senagore: And it may be a good education piece for providers too, to be able to tell their front desk that they need to be a little bit more careful about these kinds of situations.

Dr. Polansky: Well we'll bring that back.

Dr. Senagore: Thanks.

Dr. Azocar: Yes. What are the implications or the relation from these RAC Program to the current audit going on within Medicare and Medicaid now for the providers.

Dr. Polansky: One thing that we're very sensitive to is we don't want to expose providers to the same claim in multiple venues. So one contractor looking at it and another contractor looking at it, both requesting medical records. So to prevent that, one of the cornerstones of this program is setting up a data base, where any claim that has been reviewed by any of the standard Medicare contractors are put into that data base, and before a RAC can go look at a claim, they need to make sure that it's not under review anywhere else. So that'll prevent the redundancy and the aggravation of the provider. The claim can only be looked at once. Does that help answer your question? I should have framed the question. What I'm answering is the issue of will a provider be exposed to multiple contractors asking questions about the same claim, and the answer is no. There's infrastructure being put in place to ensure that doesn't happen.

Ms. Combs: And another piece of that answer, that relationship between the regular claims processing contractor and the recovery audit contractor is that we're going to be looking to the carrier, the FI, the DMERC to be looking at the claim data that the RAC produces. Look at the areas where the

recovery audit contractor is finding overpayments, and evaluate that data and analyze that data, and figure out if there is anything that they the carrier, FI, DMERC need to do differently in their system. Maybe they need to put in some new prepayment edits to capture things that are sliding through the system. Maybe they need to do a better job of educating the provider community. We're really looking at this tool—I'm looking at this tool as wonderful way to help encourage that error rate to sneak down in these three states, through provider education and better edits. We're hoping that that's what we see and that's what I'm sure will be a very big part of the report to Congress is what happens to the error rate in these three states.

Dr. Leggett: You've been pretty clear about your intensity and looking at overpayments. What's your strategy for underpayments?

Ms. Combs: The statute does require that the recovery audit contractors identify underpayments. They don't get any sort of fee, they don't get any contingency fee or payment for identifying underpayments, but they will be notifying us at CMS, and we will be passing along that information to the carrier, the FI, the DMERC, who will then ensure that correct payment is made to the provider. What we have seen from our CERT results, Comprehensive Error Rate Testing results, the improper payment results, is that underpayments happen very, very, very infrequently when you're not talking about E&M services. The majority of the undercoating that does occur in Fee for Service Medicare occurs at carriers and within carriers it occurs in the E&M services. So because that's the piece that's being set aside and not going to be on the table for the recovery audit contractors, those one level or two level differences. We don't anticipate that there will be very many underpayments at all, that they identify. But when they do identify them, they will let us know, we'll let the carrier, the FI know, and correct payment will be made to the provider.

Dr. Przyblski: Just one of the facts we learned on our road show, the actual rate of under payments in the Medicare Program is less than .05%. Do you see that with E&M-codes?

Ms. Combs: No, with E&M-codes, it gets up to .67%. It's still less than one percent. It's still a very small number of the allowed dollars coming in.

Dr. Polansky: But it is built in the program—we heard a lot of questions on the road about that. And clearly, as the contractors are looking through claims, they're going to find these things. And it's their obligation to refer those over. We also think there's a broader, sort of strategic agenda. This is a demonstration project. Creating goodwill with the provider community as best as that can be done through

this kind of process, is clearly going to be an imperative for the contractors. As three years from now, when Congress is looking at this program. So in terms of provider satisfaction, and an even-handed approach, we do expect them to be sensitive to this issue. If they do come across overpayments, they are going to spend the time and energy to make sure they forward them on to the agency. Clearly the focus of their activity is not going to be on that. Their focus is going to be different if it was an underpayment situation. But they're sensitive to this issue. We've heard that concern loud and clear, and the referrals will be made. We're fairly confident of that.

Dr. Przyblski: I have some concern about a comment that was made, although I'm appreciative that you're requiring clinicians to review these things, you also made a comment that that would be a minimum at an RN level. And I've had interactions with CMDs where they have provided me with surgical claims for me to review and this is a physician who has looked at them, who is uncomfortable making the call, and me, as an expert in a subspecialty field unable to make that call. I don't know how I can see an RN level person make the call when a physician is unable to make the call who's out of that specialty and how would you address that?

Ms. Combs: I believe that just like at carriers, FIs and DMERCs, the same is going to hold true at recovery audit contractors. The vast majority of the claims that they choose to review, do medical record review on, can be handled at a nurse level. But there will be a sample of them where a nurse is not able to make those determinations, and there will have to be some sort of a structure within the recovery audit contractor, if they're going to be successful at upholding these decisions on appeal. And if they're going to be successful at making accurate determinations through our internal control process. They will have to have some kind of a system to either set them aside and say, that's too grey, I'm not even going to go there, or I need to refer that to a physician, or I need to refer that to a specialist.

Dr. Polansky: Let me amplify on Mel's response there. The contract language is clear that the contractor needs the necessary skills to adjudicate whatever claims they decide to undertake. So the more clinically complex those claims are, the more clinically complex the cadre of professionals they need. And if you look across the spectrum the contractors in the three states, the ones that have suggested at some point in their engagement will be looking at more clinically enriched issues, tend to have much more clinically enriched teams, which is the expectation of the people who reviewed the proposals and the

expectation of the people who are going to provide oversight of this. So in fact they migrated to look at some sort of complex transplant situation, and the expectation would be that they would have people with sophisticated expertise in transplantation exercises. The New York experience, Connelly, which is different than the other two contractors, and it was selected, to some degree by design to have different kinds of experiences, does not feel at the outset that they're going to be focused on particularly clinically enriched issues. They are going to be looking at coding issues and other kinds of things that require a different set of expertise, and that's the cadre of professionals they have. And what they did assure the New York audience, if they did migrate toward more clinically enriched issues, then they would leverage the necessary clinical teams. And so some contractors have a fair amount of pharmacy talent, in terms of a rich reservoir of people with pharmacy expertise, and there obviously, part of their consideration is looking at those areas. So one thing we're going to be looking at very carefully is to make sure that the skill set is matched to sort of the activities that they're focused on.

Dr. Senagore: Could you show us what the top two or three issues are in terms of overpayment?

Ms. Combs: They have not identified any overpayments yet.

Dr. Senagore: Or error rate, that you mentioned of 10%?

Ms. Combs: I can, can I do that off the top of my head?

Dr. Senagore: Or website, or something that I can—

Ms. Combs: I can certainly tell you to get the report. You can go to www.cms.hhs.gov/cert, like Comprehensive Error Rate Testing. And from that website, there'll be a place that you can click for reports and it'll say you're now leaving CMS and you just keep on clicking and you'll be able to get the November 2004 Improper Medicare Fee for Service Report. And that gives you pages and pages of where the errors are occurring.

Dr. Senagore: It seems perplexing that given all the coding software out there that there could be truly 10% of errors in coding. That we're able to get through everybody's software for that level. So that would be a treat to see what those actions are.

Dr. Castellanos: Are there any other questions? Dr. McAneny?

Dr. McAneny: I think it's interesting that the number of downcodes are so small, but I also am wondering whether or not you're going to separate out when the miscoding was simply an error as opposed to flipping over into the fraud arena.

Ms. Combs: Any time that the recovery audit contractors identify potential fraud, they have to let go of the case and turn it over to the appropriate benefit integrity unit. Whether that's at the DMERC or whether that's out of PSC, whoever it is that's supposed to be working up fraud cases, they have to turn it over.

Dr. McAneny: My other question is as your looking at the cost of administration of this demonstration project. You'll look at what is expended by the RAC. But also by CMS. Are you including in that cost the amount of money that's going to be spent by the hospitals and physicians in defending themselves since the RAC gets some of the money when they decide that their case is justified, and that there was indeed an overpayment, and they get, I believe, 50% of that, it would also seem fair to me that if the physician and hospital successfully defend themselves, the RAC should have to pay that hospital the cost of that defense.

Ms. Combs: We will certainly be looking at the hassle factor on the provider, the costs and the time and money and the resources that they're having to expend to deal with the recovery audit contractors. That will certainly be part of the report to Congress.

Dr. McAneny: Because I'm very concerned that with the current reimbursement situation and the concerns that we've already voiced here about fewer and fewer physicians deciding that they want to work for Medicare patients, that if this becomes very widespread and becomes a routine cost of doing business, as defending yourself from the local RAC, then a lot more physicians are going to say forget it. Why do I need this? I'll just work one-third less, make one-third less money, and spend more time with the family.

Dr. Polansky: I think, as Mel was saying, in terms of looking at the success of the program, we're going to be looking at the direct, and indirect, costs of all the parties involved, and that include the physicians, but what we also have to emphasize, this program follows the same processes and rules of conventional Medicare, and so if you file an appeal to your carrier, my understanding is that you don't get reimbursed for your time and energy. So it's important that we follow the same parallels, so there will not be an accommodation on that, because we're obligated to follow the rules.

Ms. Combs: And it's also my understanding that there are some new changes to the appeals process, I want to say in the May 9-35 or 9-37 something like that, that says that when a provider files an appeal, that stops the collection process. And those same rules will apply with the recovery audit contractors.

Dr. Polansky: The final thing to sort of mention on that, is one of the things Connelly in New York communicated to the audiences when we were up in New York was that it's in their best business interest to really minimize the number of appeals. It's expensive to them. They don't recover money if it's overturned, and it's really their expectation that very few of the claims will actually be challenged. That they'll be in such areas that everyone will agree it's black and white, like two claims were submitted for the same service and the system identified double payment. But areas that are not going to create a lot of appeals momentum. And we hope that's the case.

Dr. Senagore: It's probably too late to change the acronym, but for a government oversight committee, the RAC has a somewhat onerous…[laughter] connotation.

Dr. Castellanos: Again, I'm living in Florida, so we are directly impacted here, and I can tell you that there's a lot of anxiety in the state of Florida. Experience in other sectors of the economy with recovery audit contractors and that experience has showed that most of them are very overly aggressive and very intimidating and I don't know what you can do to stop that, but I think you need to lower that, especially in the three states where you're doing the demonstration project. In Florida we were told at least by the FMA that you were going to go back at least one year, but now you're going back three years from March 2005?

Ms. Combs: The recovery audit contractors have been given the prior three years worth of data. They are not allowed to look at claims in the current fiscal year. Those are the claims that the carriers and the FIs today are busy doing their claim review on. So not counting this fiscal year, but going back the prior three years.

Dr. Castellanos: And then it's a three-year program, so they really going to have a six-year window to look at, is that correct?

Ms. Combs: That's a good way to look at it, yes.

Dr. Castellanos: Now my understanding is they're going to focus based on hospital claims and outpatient procedures.

Ms. Combs: Initially, they will be all focusing on inpatient hospital claims and I don't know what they're going to be doing after, and I don't know if that focus will take them one month, one quarter or all three years, but whenever they decide that they're ready to focus on something else instead of inpatient hospital, or in addition to inpatient hospital, they will come to us and let us know and we will let the provider community know.

Dr. Castellanos: Just the experience with E&M-coding, I know you're not looking at that specifically, there's a urology company that does that, and I spoke to them yesterday just to find out what their experience is and they feel that there's at least a 20 to 30% undercoating on the E&M-codes. I'm not sure if you are familiar with that, but I can give you that reference the person to talk to.

Ms. Combs: Sure, I appreciate it. Like I said, with the CERT data, the majority of the undercoating situations in Fee for Service Medicare happen with E&M services. So it does not surprise me that that data is out there. But it still is a much smaller percentage than the overpayments that we see.

Dr. Castellanos: Are there any other questions? Dr. McAneny?

Dr. McAneny: Yes, I'd like to follow up on what you just said. One is that there are at least in oncology now, there's a whole industry of people who are saying you guys have been really sloppy on your coding and you're undercoding, you haven't bother to capture all the charges you potentially could. There are companies out there who are successfully making their living at doing proper coding and saying you have been billing this level. You've avoided these things, then come up to a certain level. So I think that you're seriously underestimating, at least on the physician outpatient side, the amount of undercoating that is really going on. And I would also like to make a recommendation if that's in order.

Dr. Castellanos: Please.

Dr. McAneny: I would request, I would have PPAC request CMS in their evaluation of the RAC demonstration project, weigh the cost of administration of the demonstration project, expended by the RAC, by CMS, and by the hospitals and physicians in defending themselves against the amount of money recouped by the RACS. And if a physician successfully defends themselves against the claim, the RAC must then reimburse the provider. And to speak to that for a minute. I know what you said in terms of we're following the Medicare rules, but we're not. Because we've never had a rule where someone other than Medicare recoups any of the money when they successfully find an overcoating, so we're not following the

existing Medicare rules, we're making a new one. So as long as we're making a new one in favor of the RACs, it seems to me we ought to be able to make a new one in favor of those people who may have to defend themselves against the RACs.

Dr. Castellanos: Is there any discussion concerning Dr. McAneny's motion?

Dr. Polansky: Her suggestion is understandable and we'll bring it back and sort of see what kind of accommodations are present.

Dr. Castellanos: Dana, can you read that back, please?

Ms. Trevas: I need a second.

Dr. McAneny: And if a physician or provider successfully defends themselves against the claim, or however you would state that, the RAC must reimburse the provider for their expenses. Not CMS. It's the RAC who would have made the mistake in saying you over coded this, I say no I didn't. I turn out to be right, but I've had to spend a huge amount of time and effort defending myself, and money, well time is money. But I should be able to get those costs back.

Dr. Polansky: Can I ask a question?

Dr. McAneny: Sure.

Dr. Polansky: Because one of the things we are hearing is this sort of issue of fair play and symmetry. Would you be interested in the reverse, too, that if the RAC prevails, then you would be interested in paying their administrative costs in administering the appeal proceedings?

Dr. Castellanos: They're getting paid on a contingency basis.

Dr. Polansky: This does add to their costs, though, I think they have factored this in, and made judicious decisions to really limit the amount of appeals. But in the interest of symmetry.

Dr. McAneny: Do we end up paying penalties for an over payment. I mean it sounds like we already are paying those kind of things.

Dr. O'Shea?: You don't just pay it back, there's penalties, also, aren't there?

Dr. McAneny: Or is that just fraud.

Ms. Combs: It's my understanding that there might be some interest depending upon how long it takes to pay back the over payments, but I'm afraid I'm not an overpayment expert. So I don't know all those penalties.

Dr. Castellanos: The over payments are due within 30 days.

Ms. Combs: I think that's right, something along that line.

Dr. Castellanos: Over payments are due within 30 days.

Ms. Combs: And I do know this. Providers will still have the option to choose to pay back those overpayments through the offset process, so that choice will not go away. That will still remain an option.

Dr. Castellanos: I guess we have a motion on the floor. Dana, could you read that back to us please?

Ms. Trevas: PPAC requests that CMS in its evaluation of the RAC demonstration project weigh the cost of administration of the project against the costs expended by the RAC, CMS, and providers or physicians, and if physicians or providers are successfully defend against a RAC claim that the RAC reimburse the provider for their expenses.

Dr. McAneny: Not quite, because what I want the costs to include are not just CMS's costs of administrating the demo, but how much of the dollars that go into the healthcare industry. So it's the costs expended by the RAC, and by the hospitals and physicians. The whole cost of this system needs to be evaluated to find out if it's worth it, if we're spending billions of dollars and recouping $100,000 in errors, why bother?

Ms. Combs: Could you just read the tail end of that to make sure that I'm clear?

Ms. Trevas: I think I do have that capture in there. PPAC requests that CMS in its evaluation of the RAC demonstration project weigh the costs of administration of the project against the costs expended by the RAC, CMS, and providers and physicians—

Dr. McAneny: Not against. The costs of administration by CMS, by the RAC, by the hospitals and physicians, against the amount of money that they recoup so your balance sheet is different.

Ms. Trevas: PPAC requests that CMS in its evaluation of the RAC demonstration project weigh the cost of administration of the project by the RAC, CMS, and providers and physicians, against the amount of money recouped, and if physicians or providers successfully defend the claim against the RAC, the RAC must reimburse the provider for their expenses.

Dr. Castellanos: Is there any further discussion?

Dr. Azocar: It may be a little more complex, because sometimes so to speak the penalty, or the overpayment or the underpayment may be like say $100 and then at the end, when you review everything, you come out that is 75 or 25. So it's kind of not clear what side will take what recover the legal expenses for example, which is very expensive for the provider, to get legal expenses to go over all the things. It's not black and white all the time.

[Chatter]

Dr. Castellanos: Should we add to that motion?

Dr. McAneny: We should probably split it.

Ms. Combs: It would help CMS if you would split it into two. I can just tell our response is going to be easier if you split it into two.

Dr. Castellanos: Why don't we do that?

Dr. McAneny: So let's split it into the evaluation of the RAC demonstration project, and lets weight the costs of administration of the demonstration by CMS, the cost expended by the RAC, and the costs expended by the hospitals and physicians in defending themselves, against the amount of money recouped by the RACs. And stop it there.

Dr. Castellanos: Let's just stop it there. Does everybody understand that? We're splitting it. I'll call the question. All in favor?

[Ays]

Dr. Castellanos: Opposed? And the second portion of that recommendation? Melanie could you, Dana could you read that please?

Ms. Trevas: PPAC recommends that if a physician or a provider successfully defends against a RAC claim, the RAC must reimburse the provider for expenses.

Ms. Combs: It would be helpful if you could get the word *appeal* in that sentence somewhere, because I think that's what you're talking about, is defending an—

Dr. McAneny: Successfully appeals the claims.

Ms. Combs: That would work better.

Dr. McAneny: OK.

Dr. Castellanos: Could you read that back then, Dana?

Ms. Trevas: [off mike] that the claim made by the RAC—

Ms. Combs: Read the sentence one more time and I'll listen carefully.

Ms. Trevas: PPAC recommends that if a physician or provider successfully appeals a claim made by a RAC—

Ms. Combs: How about a claim determination made by a RAC?

Ms. Trevas: The RAC must reimburse the provider for expenses.

Ms. Combs: And did we get the word *appeal* in there?

Dr. McAneny: Yes. Successfully appeals.

Dr. Castellanos: Are there any questions?

Dr. Senagore: I was going to call that motion. I'm sorry.

Dr. Castellanos: Seeing none. All in favor of that motion?

[Ays]

Dr. Castellanos: Opposed?

Dr. Senagore: One other comment. Will issues related to teaching guidelines be included in this review? Is this another way to back into another path-otic[?] go round?

Dr. Polansky: I think we'll get back to you with an answer on that. That's a good question. Can I just clarify one thing? The issue of appeals and the issue of stays on recruitment is somewhat complicated because we're in the midst of, there three things going on. There's sort of historically how appeals were handled, there's a current policy, and then there's a regulation in progress. So it created a fair amount of confusion in New York. We'd ask for your consideration, we'll provide you a written statement of how the appeals and recoupment is working currently and where it may be projected to head in the near future is that's OK.

Dr. Castellanos: Why don't we make that as a recommendation, asking you that PPAC recommends that you provide us with the appeal process…

Ms. Comb: My belief is that the appeal process for claims denied under the RAC process are not going to be any different than the appeals process for claims denied by a regular carrier, FI, DMERC. Am I correct?

Dr. Polansky: Correct.

Ms. Comb: So what you may be asking for a broader education piece from CMS at some point about all the changes that are happening in the appeal process, not just limited to just RACs.

Dr. Polansky: It is evolutionary ground. I just wanted people to be aware of that because it has created some confusion. Especially as it relates to recoupment, and I think the way it works is currently as it could change as the regulation unwinds, if you do appeal within 30 days it puts the recoupment on hold. But we will give you a clearer statement on that, because I know it created some confusion when we were on the road.

Dr. Castellanos: Are there any other recommendations?

Dr. McAneny: One of the problems that's been identified is that we get surveyed to death. We get all kinds of pieces of paper that are designed to look remarkably official. Some of which are from various drug companies, others are from people who want to survey our prescribing habits, and so it's difficult sometimes to know which ones should go directly to the trash, and which ones one actually has to follow. And one of the concerns is with the difference, and we talked about this at PPAC before in trying to just get information out to physicians, things go to the billing address, the physician never sees them. All these kind of communication errors occur. So I think that it is really crucial in trying to do this that the RACs with CMS's help, so that we know that they are an official company and not somebody who wants to sell your prescribing data to the pharmacists, which that would never happen, I know. But we want to make sure that this is obviously an official CMS project and that it goes to the correct address, and it goes actually to the physician and we need to make sure that that happens because otherwise it's going to go to the trash someplace, and then you haul us off on handcuffs because we didn't do the appropriate response.

Dr. Polansky: There are a lot of questions in there. I'll field a few of them and I'll answer the issue of making sure we have the right addresses. In terms of getting the message out there that people may be getting letters from these new contractors and it will be on the contractors' letterheads. So in New York, for example, it would come on a Connelly letterhead, which is certainly going to be very foreign to the providers and the practitioners that may be receiving those. So we're spending a fair amount of time getting the message out through the professional societies, through the trade organizations, etc. so people have some awareness of what's happening. We think that's terribly important. We're going to do our best and in fact one of the questions of the Council is, if you have other ideas about communication pathways and

portholes that we should be using to get this message out, we're very receptive to hearing that. The other thing that Mel's going to tell you we've learned through the CERT program is this issue of letters being misdirected or going to the wrong place and then the clock's being affected and penalties and interest and such, is something we're also moved farther up the learning curve and Mel's going to answer some of the processes we'll be implementing for the RACs.

Ms. Combs: Yeah. The recovery audit contractors came to town the other day and met with CMS and the carriers, FIs, DMERCS, and QIOs from the three states, and they were concerned about the provider address issue. And anybody that listened to the Open Door Forum where we talked about this issue knows that addresses continue to be a problem in the CERT world and will likely be difficult to deal with in the recovery audit contracting world as well. But we have tried to share with the recovery audit contractors the experiences that we have had in the CERT world. The mistakes that have been made, and the new positive things that we're putting in place, to help make sure that we get the correct address for the physician. For example, now, before a CERT request for medical record letter goes out, a phone call is made to the provider to say I'm getting ready to send you this letter. Here's the address I have on file, is this the right address or would you like me to FAX it to you so they get all that contact information before they actually submit the letter. That entire data base of provider addresses correct provider addresses, will be made available to all three recovery audit contractors and we think that will be a big help to them. We also shared with the recovery audit contractors a tool that we used in the CERT program to help the provider community recognize that this an official important letter that needs their attention, and that is in the CERT program, we have what's known as the Melanie letter, which is basically a letter from me that has CMS logo on it that says welcome, you've been selected for CERT review, lucky you and here's what the CERT program is all about and here's why it's really important that you respond. And then comes the letter from the CERT contractor with all the details about which medical records in which states of service and all that stuff. We're considering doing the same thing in the recovery audit contracting world. Instead of being a Melanie letter, it might be a Jerry Walters letter, because he is the lead of the RAC project, and it likely might be a letter that says, with CMS logo on it, welcome, you've been selected by your friendly neighborhood recovery audit contractor. This is really important. This is official CMS stuff, please respond to their request for medical records. So we do believe that some of the experiences that we have had in the

CERT program will help us to identify and get to the right physicians. I would also suggest that we will have a similar problem a year or two or three down the road when it comes time for our evaluation contractor to try to take a pulse of the provider community and measure the hassle factor, the costs the kinds of things that we were talking about earlier. We may need to come back to you at that time and ask for some suggestions from you about how best to reach out to the provider community and make that assessment at that time. That's a little bit different kind of problem than reaching the individual provider, medical record department. And it may be a little too early in the game to talk about that now, but you're exactly right. We want to make sure that whatever the efforts are, to assess the provider community, don't get thrown in the trashcan.

Dr. Polansky: Let me add one other thing. One of the standard business practices of at least Connelly in the New York demonstration is their standard protocol is to actually call the provider or practitioner prior to sending the letter and saying this is what we have found. Take a look at what we have found. Get back to us. Let us know what you think and also at that point to verify addresses. So there's a higher likelihood that when the letter comes, if it actually leads to that, that the provider or practitioner is ready to understand who it's coming from and what the context is. That is not required by contract, but in the spirit of making this program work, Connelly actually thinks that's a good investment of their time, and the byproduct of that is hopefully very low appeal rates as well as good provider communication.

[Off mike comment]

Dr. Polansky: We can bring that back. I suspect their answer may be that that's prohibitively expensive, but that tends to sensitize the provider that it's a much higher priority. We'll bring that back. That's an interesting idea.

Dr. Castellanos: Are there any other recommendations or questions? Dr. Senagore.

Dr. Senagore: PPAC recommends to CMS that issues related to teaching position guidelines be specifically excluded from the RAC purview for claims determination.

Dr. Castellanos: Is there any discussion on that motion?

Ms. Combs: Could I just ask why?

Dr. Senagore: A, we already went down that road once, with the PATH audits, about 5 or 6 years ago and it came up glaringly to be a major burden, not only in teaching facility, but actually that there

weren't many issues that truly got all the way through the process, B, there's already a process in existence for that, and C, I don't think it's terribly clear exactly how those need to be applied, so I think you're in the same quagmire that you are with E&M guidelines, and those are off the table.

Dr. Castellanos: Is there any further discussion on that motion? Dana, can you repeat that for us?

Ms. Trevas: PPAC recommends that issues related to teaching position guidelines be excluded from the RAC purview for claims determination.

Dr. Castellanos: I'll call the question. All in favor?

[Ays]

Dr. Castellanos: Opposed? Are there any other questions?

Ms. Combs: Could I make a suggestion to PPAC? I think as CMS tries to evaluate that recommendation and tries to determine whether that is something that we should adopt or not it would be helpful to have something in writing, even just a very short statement, about the rationale in terms of why you think that is something we should do. As you know, before we made the decision to take the E&M-codes off the table, we had an AMA Resolution 819. Again, not a long statement, but just a short statement of why they felt that it was important to handle reviews differently. And I think it might be helpful to have something in writing from PPAC or some OIG Report or some document that sort of outlines what the issues are with teaching guidelines.

Dr. Polansky: What we heard very loudly and very clearly from the contractor, things that are low yield and high ambiguity are not where they're going to be focusing their limited resources, so if in fact that's the backdrop from that, there's sort of a self-corrective process built in to sort of this incentive based program we have. It really forces people to focus on areas of high clarity and high yield, and so if this issue is in fact low yield and high ambiguity, it's exactly the kind of thing they're going to steer clear of.

Dr. Senagore: But let me just clarify. So if a code gets submitted without the GC modifier, even though GC doesn't imply payment issues, and it's not clear, even though it's not clearly articulated what is appropriate level of documentation, but if there's some issue about whether or not teaching guidelines were documented, they'd know, would that be considered an error in payment for not using the GC modifer.

Ms. Combs: I don't know the teaching guidelines well enough to answer the question. Do you?

Dr. Polansky: I can't speak to that.

Dr. Senagore: Hence the ambiguity. I mean you folks—

Ms. Combs: But I would be that way on any, I'm just not a policy expert.

Dr. Senagore: Right. That would be the challenge. Because we went through this whole issue with the PATH audits 6, 7 years ago, and everyone remembers what a quagmire that turned into and initially it was a witch hunt, and then as it turned out that people got through the process, there wasn't really that much "error" existing in the processes. And so it could be another go at that same, and it would be a tremendous burden at teaching facilities to again go back through and try to figure out what the appropriate documentation is for those issues.

Dr. Castellanos: Maybe you can provide that information to CMS for their answer to this.

Dr. Senagore: I think they can just look at their track record on the PATH audits and see where that went.

Dr. Castellanos: I think she's asking for us to make a supplement. Are there any other recommendations? Dr. Urata?

Dr. Urata: Well, I agree. I think we should add Dr. Senagore's reasons into what we just passed, and we can just add on just for the following reasons, 1, 2, 3, maybe 4, and add that to what we just passed.

Dr. Castellanos: Would you prefer it that way or would you prefer a separate—

Ms. Combs: Either way.

Dr. Polanksy: Yeah.

Dr. Urata: At least they could look those four, three or four reasons in—

Dr. Castellanos: Maybe you could do that?

Dr. Senagore: I'll see if I can get something together.

Dr. Castellanos: While you're doing that, are there any other recommendations? Dr. Powers.

Dr. Powers: PPAC recommends that CMS and the RACs notify the provider community of each new area of review, such as moving from hospital to the outpatient setting.

Dr. Castellanos: Is there any discussion on that motion?

Dr. Polansky: Just for informational purposes, that's exactly how we plan on following new areas, to give people lead, to give people an understanding, but we [inaudible] recommendation, [off mike].

Dr. Castellanos: There's a motion on the floor. All in favor of it?

[Ays]

Dr. Castellanos: Opposed? Thank you. Dr. Simon you had your hand up just a few minutes ago.

Dr. Simon: Just one quick question. For the current demo, where there are three states involved, will each state maintain its own database, or is there a common database between all states involved?

Ms. Combs: It's a common database, but each contractor only has access to see their claims. So the carrier in New York can only see New York carrier claims. They can't see the DMERC claims from California.

Dr. Castellanos: Dr. Senagore, do you have those?

Dr. Senagore: I think it would be easier if I just send the document. I'll get the courier to do it by the mail.

Dr. Castellanos: Are there any other recommendations? Dr. McAneny?

Dr. McAneny: I'm still bothered by the question about under [inaudible] because you only find things if you look for them, and if it's of no benefit to you to look for them, then why bother? So I'm struggling to try to get, PPAC recommend that when CMS is reviewing the RACs, they make sure that under payments are evaluated and reported appropriately. If they're going to report back and then the up code will go to increase payment, I think that would be fair.

Dr. Castellanos: There's a motion on the floor, Dana can you repeat that motion for us?

Ms. Trevas: PPAC recommends that when CMS is reviewing the RAC's performance, CMS makes sure that under payment issues are evaluated and reported appropriately.

Dr. Castellanos: Is there any other discussion on that motion? All in favor?

[Ays]

Dr. Castellanos: Opposed? Is there any other further discussion? Dr. Polansky and Ms. Combs, we certainly appreciate you coming here today. Dr. Polansky I know you were up in New York on Thursday when I spoke to you. You mentioned you were coming to Florida next week?

Dr. Polansky: I think in two weeks we'll be in Orlando.

Dr. Castellanos: Well, you need to let the medical community know and Dr. Jim Cochran, the Carrier Medical Director would like to meet you too. I had some discussion with him. OK, thank you. Next discussion if the National Provider Identifier Update. Ms. Kimberly Brandt is the Director of the Program

Integrity Group for the Centers for Medicare and Medicaid Services. Prior to joining the Program Integrity Group, Kimberly worked for over five years for the Office of Inspector General on a variety of progressively challenging jobs. As a senior counsel in the OIG's office of Cousel, Special Counsel for External Affairs, and Director of External Affairs.

National Provider Identifier Update

Dr. Castellanos: CMS asked me to present three questions for our next speaker on the NPI update. The first question is will there be a provider directory for NPI's for community access? If NPIs will be replacing the UPIN, this information is critically needed for us to be able to bill Medicare and other health plans as referring physicians ID numbers required. In our case, we are very limited access to referring physicians, and it would be nearly impossible to get the numbers from the physicians directly. How do you anticipate handling this. Second question, we are a group of 100 providers. Would you recommend that we file each individual application electronically or wait for the electronic file interchange process to be in place before we apply for NPIs? We want to be ready to comply if health plans decide to implement NPI sooner than later. Do you have any health plan information as to when the large carriers thing they may be instituting these changes. And third, if a patient with a primary health plan has that put in effect, the new NPIs and a secondary health plan that has not, or visa versa, what is being done to assist the providers in getting claims paid timely and accurately since it was not mandated as to when everyone would be ready to convert and accept NPIs?

Ms. Brandt: Well thank you for having me here today. This is an important day for us at CMS because today, May 23rd is the deadline we had set for ourselves to begin enumerating providers with the National Provider Identifier. Just to kind of set of the stage, what I'd like to start out by doing is just give a very brief background of what the NPI is and why it is that it's going to be required, then give you an update as to our current status, and then talk a little about outreach and some of our future plans, in addition to addressing the three questions that were just posed and any other questions that you might have.

First of all, to give you a little bit of background, when the Health Insurance Portability and Accountability Act was passed, back in 1996, one of the things that was included in there was that eventually CMS and all HIPAA covered health care providers would be required to have what's called a National Provider Identifier. It's a unique 10-digit number that is going to replace all of the other

identifying numbers that we at CMS and the other health plans and the others have for providers to deal with. So effective May 23, 2007, two years from today, the NPI is going to be your one and only number. All practicing physicians will just need the NPI. They won't need the UPIN number, the OSCAR number, the Medicare Number, health plan number, whatever other numbers that might be out there for any kind of standard transaction that physicians or other HIPAA covered entities would engage in, the NPI will be the only number that will be required, which at least conceptually seems like it will be a lot easier than keeping track of all those other different numbers. What our plan was as we kind of moved up to today's date, was to look at ways that we could make it so that applying for, receiving, and transitioning to the National Provider Identifier would be as painless and seamless as possible. To that end, we have been looking long and hard at the provider enrollment chain operating system, or PECOS, which many of you are painfully aware of from the past few months, which was our enrollment system, that we had for CMS, where we were trying to convert all of our contractor enrollment systems over to a standard uniform enrollment system across all of the contractors. I know that many of you had either a personal experience or had colleagues who had experiences with the PECOS system where we had long backlogs, problems with people getting the numbers and other types of issues that have occurred, and what I'd like to walk you through today as part of my remarks is how we are hoping to prevent the NPI from being what I deem the son of PECOS, or PECOS II. [laughter] We are hopeful that we have learned our lessons from PECOS and that we will not have a similar experience. And one of the things I'll be focusing on is ways that we have indeed learned from that. The other thing that we learned as we were preparing for the NPI today is the types of outreach that we should be doing with the physicians. We learned not only from our PECOS experience, but also from the recovery audit experience, that Melanie and Jesse were just talking about, and some of our other interactions with the physician community over the last year. Sort of what works and what doesn't work in terms of outreach and reaching out to the physician community and to other health care providers, as we prepare to get the NPI ready to go live today.

So along those lines, let me now talk to you a little bit about what our current status is with the National Provider Identifier and address some of the ways that we have had what I call lessons learned from PECOS and how I think and hope that this will make it so that the National Provider Identifier will be a much more easy to use and seamless system. One of the first concerns that we had when we really looked

at what caused the problems behind PECOS was that there hadn't been enough thought given to the volume of providers who could be on the PECOS system at any particular point in time. We really hadn't thought about the volume issue. We had, but conceptually you can think about it, but it's another thing to experience the reality of 100,000, 200,000 or more providers all trying to get into a system at the same point in time. The system, quite frankly was not prepared for the volume of enrollments and reenrollments that we had at that particular point in time, particularly since all of that had to occur through the contractor. There was no web-based system so that the provider could go on and enter the information themselves. They had to submit everything through a contractor. The contractor then had to reenter the information, and because we were combining several different systems into one uniform system, there were also transition issues. We had assumed that we would be able to convert a certain amount of old data to the new system. It turned out that at least initially that was not the case. We had assumed that we would be able to have a faster turnaround time for entering information and getting that new information in place. It turned out it was taking two to three times as long as we thought it would to get that information. Keeping all those things in mind, when we were working to develop the National Provider Identifier system over the past year, the very first thing that we decided to focus on was to make sure it was a web-enabled and web-based system. So that that way and we hope to have a demonstration here at noon today with hopefully a couple of you will participate in, to show that you could go onto the web, enter the information, and send it in yourself, or have a practice manager from the practice enter that information. Or have other ways that we could go ahead and enumerate people by providing that information through the web to make it a little easier. That way you don't have to rely on the contractor, and there doesn't have to be that level of interface. Another thing that we really focused on as we were doing the testing of the system was stress testing, or burden testing. How are we going to make sure that we can have it so that we can have capacity for a certain amount of users to be on it any given point in time. With PECOS the system overloaded when we reached about 4 to 5,000 providers sometimes at one point in time when we had all the contractors trying to get in. With NPI, at least as of our stress testing for last week, we are now able to accept up to 10,000 providers at any one point in time being on line, which again, we're hopeful that we've got a 2-year implementation period here, we won't have 10,000 people on line every minute of every day from now until 2007. It will be phased in. But it seems that 10,000 is enough; that that gets us to where we need to be

at any given point in time, we can have up to 10,000 people on line and it doesn't seem to cause any burden to the system. If we find that we need to increase that number over the course of the next few months—that's something that we're also prepared capacity wise to be able to look at so that we can adjust that to meet any workload issues that might occur. The last thing that we had learned from PECOS was that we had a lot of communications gaps. Not only were there communication gaps with the contractors, but there were a lot of communication gaps with the provider community at large. We realized that the provider community was not really ready for PECOS. They didn't realize exactly what was happening or why PECOS was occurring, why they needed to have that enrollment system in place, why we were reenrolling. We also realized that the contractors were giving different answers. Empire might say one thing, Trailblazers might say another, these are just examples, not specifics. But we would have different answers that we'd be given and that was causing even more frustration and confusion amongst the provider community. In terms of our outreach plan, we've taken steps to make sure that we have a very standard script that goes out to everybody so that all contractors give the same answers. We're trying to make sure that consistent information is available both on website for the NPI in addition to at the contractor, and we're doing a lot of individual, one on one, outreach, and I'll work through that more in just a couple of minutes. But I think to at least allay the initial concerns, that at least a lot of the providers that I've talked to have had, we feel relatively confident at CMS, as confident as one can feel with any computer based system that at least NPI is years ahead in terms of technology and otherwise than what the PECOS system was. We've managed to address a lot of the kinks ahead of time We've found problems ahead of time and I'm happy to report as of well, half hour ago, when I got the latest update, the system had only been up for an hour and a half, we'd already enumerated 250 providers already this morning. And it hadn't crashed and it was still up and running. So at least as of this morning, things seem to be working relatively smoothly and we hope to keep that in place. [laughter] But with that, let me turn to some of the specific plans that we have in terms of outreach and education and talk about how a provider would go about getting and NPI and then I'll go into some of the specific questions that were posed to me by the Council, and then open it up to the Council as a whole.

As I mentioned, outreach was one of the things that we were particularly concerned about. We knew that there were going to be a lot of questions about NPI. People were going to be confused about

what does this mean for our practice? How do we go about getting and NPI? When do we start using the NPI? Do we have to get it now? Can we wait until May 22, 2007? What is the timing of this? And I think one of the things that we've tried to do is to work out a few specific guidances that we are giving to providers to help answer some of those questions. We're doing it in a number of different forms. First of all, what we did was send out through email, through the HIPAA list serve, through the trade associations and otherwise through the state medical associations, and other types of groups, a Dear Provider letter that went out under Dr. McCellan's signature the first week of May, I believe it went out May 6th officially, although they continued to go out the next week a little bit as well. In that Dear Provider letter, it outlines to all HIPAA covered providers that the NPI is coming. It's going to be up and live, on May 23rd, 2005, today, so that people can begin to be enumerated. It went through the website that people could go to to get information about what they needed to apply for the NPI. On the website, there's actually a checklist of all the items that you need so that you can fill out the application. It provides links to a copy of the application in PDF form so that people can download it and look at it and see what they need. It has FAQs on there, things that we have found, even in our initial interactions with the provider community that people have been asking about, some of the things like batch enumeration, can someone else get your NPI for you, things like that which I'll walk through in a minute. All of those types of questions were on there, and it's all in one place, so that it walks through—OK, you can get the number right away. You can wait to get the number. You can have your office assistant file the number for you. There are transition periods for getting the numbers. Sort of all of the basic practicalities sorts of things. But that Dear Provider letter was our first attempt at least to get the word out there in a formal fashion that the NPI is going to be up and enumerated and people should be on the look-out for it. Now again, we've got 2 years. So we wanted to at least get people generally aware here for May 23 of 2005 but over the course of the next 6 months, we wanted to work very closely with the provider community to give them more specific information. To that end, we are going to have a CD Rom that will go out to providers towards the end of the summer, which is a sort of View It CD Rom if you will, which is going to walk people through how to do it online. It'll basically walk people through it. It's an instructional demo. Here's how you go to the website. Here's the information that you need. Here are the things that you need to have available. Here's how it's going to work. Sort of showing someone actually getting enumerated and how it will go through the process. We're also going to

have two round tables through the Office of I think it's Electronic and HIPAA Standards now. They just changed the name on us here at CMS. But anyway, through our HIPAA Office at CMS, we're going to have two roundtables, one in June and one in September, where again, we're going to reach out and try and explain what's going on and what the NPI means to all providers. We are working on a massive outreach effort to state medical associations and national medical associations to get the word out to them. Myself, or members of our staff are going to be speaking at a number of those types of conferences over the course of the summer including the national AMA meeting in June and other types of meetings, again, in an effort to get the word out so that people understand what NPI is and what it means for them and how it's going to work. And then lastly, what we've done is in terms of consistency information that people would get from our contractors to address some of those problems that we had with PECOS, we have issued as I mentioned before, standardized scripts both in English and in Spanish, because we find we have a number of Spanish-speaking providers out there, that are all the contractors offer consistent accurate information that will be given out, hopefully is standardized across the board to all who call in to the numbers. That same script is also available at the enumerator contractor, the actual contractor who is enumerating the providers, so there is a help line at the enumerator that providers can call and get answers when they have questions as well and that same information that's at the enumerator hotline is the same information that we have provided to the contractors. So everybody is speaking the same talk and there shouldn't be any one person giving an answer one place, another person giving an answer in a different place.

Moving to some of the specific questions of sort of the concerns I guess and practical realities of getting an NPI that we had heard. One of the things that I have gotten a lot of questions about is whether or not we are going to be prepared to do, and this goes to one of the specific questions that I think was here to the group of 100 providers, should we all file individually, or can we file as a group? One of the things that we have made arrangements for is beginning this fall, probably late September, provider groups can opt either through an electronic file or through and association such as the AMA or one of the other large groups, to do what we're calling electronic file interchange. So they can file a group of 100, 200, possibly even 1,000 or more can all file for NPIs as a group. So there'll be an electronic file interchange that will occur so that four large groups, or large associations, for instance of a state medical association or others wanted to coordinate getting all the information for their group together in one place, we will have the

ability beginning this fall to do those large group enumerations. People can enumerate individually ahead of then, if they want to, but otherwise they can be enumerated as part of a large group. We're calling it a batch enumeration. So basically what would happen is the group would supply all of the provider's identifying information for everyone in that particular group. So let's say it's a state medical association. They would submit on behalf of their however many thousands of members, all of the pertinent relevant information that's on the NPI application, and in an electronic file format, that would go to the enumerator, and then the enumerator would then individually enumerate all of the people for that group. We anticipate that that is going to be something that will be very helpful, particularly for physicians who practice in very large group practices or have other associations with large groups because it will allow them to get that provider number as part of a larger group and they won't have to spend the time individually applying for their number. However, physicians who feel that they either want to get their own number ahead of time, or don't want to wait to do the file interchange will be able to go online and be able to do it I individually. The way the online application works is you go on line, you sign in and again, we're going to hopefully do a demo at noon today. You go to the website. It asks you for the identifying information and it takes about five to ten minutes to fill all the information in. Once you're done filling in the application, you submit the send button, it's sort of like you place an Amazon.com order, is the best way I can think of it. And if you haven't filled out all the information, for instance if you leave off your credit card number, but in this case, if you leave off your license number or something like that, it'll come back to you and say, No you have not submitted all the correct information. Please go back and fill out the highlighted field. Again, much like Amazon, it'll show you where you didn't fill out the information. You fill that information in, submit it, and then hopefully, depending on how many people we have getting enumerated that week or whatever, you will immediately, within about 5 to 10 minutes receive an email back that says your application has been successfully submitted. And then depending on how many people we have being enumerated that week, no longer that 3 to 5 business days after that, you will receive via email, so electronically, the same way you submitted your application, an email back that says Dear Dr. X, we have received your application and you have been enumerated. Your National Provider Identifier is the ten digit individual number that's unique to you. The one thing that I will note is that there are no vanity numbers, so you cannot request [chat] special numbers as it is a randomly generated kind of number. Just to keep people on the same page.

People called in like, you know, certain numbers apparently were their lucky numbers, but we don't have the ability to do specifically generated numbers to that effect. But you'll receive that back. For those physicians or providers who do not have the ability to either do the electronic file option, in other words, get enumerated as part of a large group, or do not for whatever reason have web access to be able to do the web application, we do have the old-fashioned paper application as well. And you can go paper if you want. Starting July 1st, the enumerator will be prepared to accept paper applications for a select group of people, including members of PPAC and some of our other pilot testers. We are doing paper applications before July 1st but to the public in general, July 1st is the date that we will officially begin receiving and giving out the paper applications. If you give a paper application for the enumeration, you send that in to the enumerator, you will receive a letter back saying what your National Provider Identifier is. So the important thing to keep in mind here is that it's a like transaction. So you submit electronically, you get your number back electronically. If you submit in paper, you get your number back in paper. And that was a question that we had from a lot of people, sort of, will we get a letter? Will we get it—no, whatever format you go in, that's what you get. The one thing to keep in mind, whether you're submitting it via paper or electronically, is that you can have, or at least our intent is to have it so that an office manager or someone else could submit that information for you. There are on the website when you sign in to get your number, it will ask you, you can do like a little password and things like that, but whoever is doing it on your behalf or on the organization's behalf to just figure out what that password is going to be and then it's just a matter of filling in all the information. That person would be the proxy of the provider if you will. There is information on the paper application that says that you certify that all information is true and whoever is submitting the application would be required to make that attestation electronically on behalf of whoever the submitting provider is. So just know that that person would be agreeing to all of that on your behalf if they submit it electronically. But we hope with all of this, it will make it a lot easier for people to get a quick response time. With the paper applications, as I said, with electronic, you would get an answer back within three to five days. I would expect to allow anywhere from five to nine days for the paper application, just by the time it takes to get the application in, get it received and get it back, you'd probably have a little more time before you would get some sort of confirmation on that just allowing for the US Mail and other vagaries like that.

With that, let me turn to the other two questions and just make sure I've answered specifically all three of the questions that were asked to me at the beginning of this. And then I'll open it up to all of you for any questions that you might have and I'm sure that there are things that I have forgotten to mention, but I think that those are the key points in terms of allaying any fears or other things that might have been lingering in people's minds. The first question was will there be a provider directory of NPIs for community access. With the UPIN, there's actually the UPIN registry that all of you are familiar with and can be used. Right at the moment it's sort of a directory of all the people that have UPINs. One of the concerns would be how people would get the information about the NPI for a referring physician. Right at the moment we do not plan to have a directory similar to the UPIN directory for the NPI. One of the things that we do recognize is that the provider community needs to have access to the NPIs particularly for referring physicians and things like that. So to that end, in October 2005, this fall, we're going to be publishing in the *Federal Register* a notice that will explain how NPIs can be obtained from other health care providers and from health plans and things like that. The notice will tell how you can get information from health care providers with whom you do business. We're still working on the specifics of all that. We're hoping to make it easy enough so that it will be relatively accessible. We may get to a point where we will have a directory. But right at the moment we don't have a directory similar to the UPIN directory in the works. So. Yes.

Dr. Senagore: I would strongly advocate that you do that, even if there's a subscription fee. Because that is one of the most problematic things when you go for a consult, is to try to track down Dr. Jone's UPIN number. And it's a significant hurdle and a big burden on practice. So even if there's a subscription fee to get access to the data base, this way you can track whose accessing them. I wouldn't want people just pulling off these NPIs willy nilly, but at least you know who accessed it, which account.

Ms. Brandt: Right. That's a good suggestion. The second one is we are a group of 100 providers, would you recommend that file each individual's application electronically, or wait for the electronic file interchange process to be in place before we apply for the NPIs? The concern was if health plans begin imposing use of the NPI before the electronic file interchange goes in place in the fall, whether or not providers would be ready. As I mentioned before, we are recommending that people wait until fall to do the electronic file interchange. We are working with the health plans. It's our understanding, based on our

interactions with the health plans thus far that none of the health plans are planning to go into compliance and have NPIs required before the fall. If indeed that happens. It is one of those things where the health plans will hopefully give enough advance notice that you would have time to get people enumerated individually before that compliance date would go. We are working with them to make sure that they are talking about ways to make sure that you can have for instance both the UPIN number and the NPI number in place on a standard transaction, at least until 2007. If they haven't converted completely to an NPI, and other transition issues, and I'll talk to you about that here in the answer to the next questions. But one of the things that we would say right at the moment is I would wait until the fall if you think that you are going to be a part of a group that's going to do the electronic file interchange. It's probably easier to just have everybody do it all at once than to try and have people doing it individually. If you find that a health plan does contact you and say that they are planning say in July or August to begin using the NPI, then it's certainly something where they should be giving you notice. We've encouraged them to give people at least a month or two notice so that the practices can plan accordingly. But we would also encourage you to let us know if you're hearing of instances like that, because we've been trying to work with them for the transition period.

The third question is if we have a patient with a primary health plan that has put in effect the new NPIs and a secondary health plan that has not, or vice versa, what is being done to assist the providers in getting claims paid timely and accurately since it was not mandated as to when everybody would be ready to convert and accept NPIs? This is an important question. And one that we've even been dealing with at CMS, because the CMS systems are not even going to be ready to fully accept the NPI until knock on wood hopefully May 23, 2007 themselves. We're still converting over ourselves. We're working with the workgroup for electronic data interchange or WEDI. They were part of our pilot testing group. We're working them to make sure than we can transition to NPI in a fairly coordinated fashion so that health plans and us and all the other entities who bill in the healthcare community are all working together. Basically what we're hoping is that everyone will have a transition period as I was mentioning a couple of minutes ago, where both a UPIN or other standard identifier and the NPI would both be in place for a certain amount of time so that basically you could use either one in a standard transaction so that it shouldn't result in any significant delay in billing. You should be able to use a UPIN and the NPI or just the NPI or vice

versa during that transition period. Again, I think health plans, as much as CMS, are working right now to get ready to accept NPI in all their standard transactions. I know there's a lot of entities who have already converted to formats where NPI can be accepted. But there are many more who have not. So the hope is that everybody will have both in place during this transition period until May 23, 2007. We have asked each health plan to have a transition plan in place so that every health plan has a transition plan so that they know how to deal with both, so that they can accept both the old number and the new number on all their standard transactions during this transition period and then again, assuming everything goes according to plan, in 2 years from today, everybody, CMS, health plans and all other healthcare providers will be using NPI as the only number for their transactions and the transition would be complete at that point in time. I think that with us at CMS, the one thing that we are planning to do, and this is important to know is that you will still continue if it's a new provider to Medicare, to apply for an enroll in Medicare, and you would still get a Medicare provider number over the next couple of years. However, that number is going to be subsumed into the NPI as of May 23rd, 2007, but the one thing that I would note that there has been a lot of confusion on is that people think that once they get in the NPI if they weren't already enrolled in Medicare to begin with and didn't already have a Medicare number that that's sort of a blanket enrollment. They would still need to enroll separately in Medicare if they weren't enrolled in Medicare before they got their NPI. Now again, for those of you who are already Medicare physicians, that's not a problem. When you get your NPI, that all gets rolled together, but if it's for instance a new physician, who may have not participated in the Medicare Program before, they would need to enroll in Medicare and get the NPI. It's two separate processes. It'll be one number, ultimately, but it's still two separate processes. And we always envision that you always still have to separately enroll in Medicare in addition to getting the NPI. It's just that it would be one number instead of two, effective in 2007.

With that I'll turn it back over and be happy to take any questions that you all might have.

Dr. Castellanos: Thank you, Kimberly for that very timely update. Are there any questions from the Council members? Dr. Senagore?

Dr. Senagore: Yes. New graduate starting practice would not get a UPIN number and NPI.

Ms. Brandt: Right, they would get—the UPIN we're hoping to be phasing out of the cover of the next two years, too, but they would still get the two numbers. And again, the goal is to eventually phase

them all out, but at least for the foreseeable future, until all of our systems at CMS are completely converted, we still need both number just to make sure everybody's getting paid in a timely manner, and that's really the ultimate goal is to have no delay in the payment time with all of this and that's why we'll still need both numbers.

Dr. Castellanos: When will that phase out period be?

Ms. Brandt: The phase out period will probably begin, I would say 6 to 8 months ahead of May 23, 2007. Again, we need the next year and a half to finish getting our claims processing systems completel converted over. And then we'll begin the phase out I would say about six to eight months ahead of when the actual NPI full implementation date ends, which is May 23, 2007.

Dr. Castellanos: May 23, 2007 is in the statute.

Ms. Brandt: Exactly. We are required by law to be 100% by then, so we are highly motivated for that.

Dr. Castellanos: Are there any other questions?

Dr. O'Shea: Kim let me bring up [off mike]. Until then the UPIN number still goes through PECOS, so you're still going to be using PECOS and you're going to be using a new computer system, and this, all in all, is going to make things faster.

Ms. Brandt: It is, ultimately, and the goal is actually, and I neglected to mention this before. We are currently working to merge PECOS and NPI together so that we have one uniform system. The goal is, anyway, one of our lessons learned from the PECOS experience, was to try and merge them so that we have all of that information together in one place. So eventually we can get it so that we hope to be able to have the PECOS and NPI systems in all one standard computer system.

Dr.O'Shea: Not to be obtuse again, but if you're going to use the PECOS system and you're going to have a UPIN, why am I having to fill out pages and pages if I already have this entered into PECOS, why is it that I just can't add on?

Ms. Brandt: That would be the goal is, to get it, so once you're in PECOS, then you can just add on and submit, however, unfortunately, right now, we are not to that point yet, where we can just dump and download all the PECOS information into NPI and just automatically enumerate everyone. So right at the moment, you're correct, it's an extra step and that's one of the things that we are working, again, by the

May 23, 2007 deadline at that point would be anyone who gets an NPI or anybody who gets into PECOS, automatically would be able to get together. You know, if you get in one, you can get in the other.

Dr. Castellanos: Dr. McAneny?

Dr. McAneny: So as a member of a group practice, will I need my individual one and one for the group practice for when we submit, say global billing for radiation therapy procedures? And then my individual one, as well?

Ms. Brandt: You're still going to need your own NPI and then your practice will have an NPI as a whole.

Dr. McAneny: What other organizations that physicians would belong to where they would have to have a separate from, if my group practice then joins and IPA, and becomes a practice affiliated with others, so that IPA need yet a third umbrella one?

Ms. Brandt: That's a good question. I'll need to double check on that. I would assume the IPA, probably, if they're billing on behalf of everyone in the group, they'd probably still need an NPI, because any entity who's a [inaudible] covered entity, technically needs an NPI. But that's a good question. I'll need to check on that one.

Dr. McAneny: And if I do a joint venture with my hospital, or with some other physician group in town to make a new entity, that then will be billing patients on our behalf, then we need that NPI as well.

Ms. Brandt: Right, so you'd have basically at that point, four NPI numbers.

Dr. McAneny: So and then we'll still need a state license number and a DEA, right?

Ms. Brandt: The state license and the DEA still are in there?

Dr. McAneny: And our social security number.

Ms. Brandt: But the states are going to be required to go to—and these are good questions, and I'm sorry I don't know the specific answers to all of them, and I don't know if Charlie. I have one of our staff here. On that one, I know that states themselves, health programs, are going to have HIPAA numbers as well, so I'll have to look and see what the state license numbers and all, how that goes. Because I know you have to enter licensing information on your NPI application. So I'm not sure if the states would accept the NPI as like the one and total number, of if you'd still need that separate number as well.

Dr. McAneny: I'm hoping CMS will sort of put pressure on some of these other organizations to eliminate some of the numbers and not just sort of add them on and add them on and add them on.

Ms. Brandt: I mean, the goal here was to have less numbers, not more. So I appreciate your point and it's a very good one and that's something I'll definitely look into.

Dr. Senagore: Just a follow up on Dr. McAneny's comment. Is it within the scope of the legislation that it could be mandated that this is a number that's used for claims submission.

Ms. Brandt: I'd need to look at the language, but that's a good. We'll take a look at that and we'll get back to you all.

[Charlie?]: The answer's yes to that one.

Ms. Brandt: OK.

[Charlie?]: Transactions like NPI [sound interference]

Dr. Hamilton: You'd mentioned that there's UPIN directory available, is that on line?

Ms. Brandt: Yes, it's an on line directory.

Dr. Hamilton: And how do you get to it?

Ms. Brandt: I can give you the website for that. I'll make sure and get that so you all have the website.

Dr. Hamilton: And if there is a UPIN directory, why would there not be a directory for the NPI?

Ms. Brandt: Well, part of it is we've had some concerns with the security of information within the UPIN directory. There has been a lot of identify theft issues and a lot of things that have been out there, and so that's one of the things. With the NPI if we do a directory, I think the user name, or some sort of sign in or some sort of other encrypted email is going to be necessary. Because one of the problem that we've had with the UPIN is that as a public access, people have been able to get access to it who shouldn't have been able to get access to it, and we've had some problems—

Dr. Hamilton: This is a major issue referring physician's billing offices.

Ms. Brandt: Well, I think that the idea of having a subscription fee or some sort of other encrypted access for the director is a good one and it's something and hearing the concerns of everyone hear about having a directory we'll definitely go back and look at that again.

Dr. Hamilton: Should we make that as a recommendation?

Dr. Castellanos: I would hope this Council will. Would you like make that?

Dr. Hamilton: I would like to make it a recommendation that CMS develop a UPIN directory that would be—I'm sorry an NPI directory that would be appropriately accessible, with security consideration being taken.

Dr. Senagore: Second.

Dr. Castellanos: Is there a second? Any further discussion? Yes.

Dr. Senagore: I would add in there for the purposes of claims submission so it doesn't end up with pharmaceutical companies calling me up.

Dr. Castellanos: Is there any other discussion on that motion? Dana could you repeat that for us, please?

Ms. Trevas: PPAC recommends that CMS develop a National Provider Identifier directory that would be appropriately accessible to physicians for the purposes of claims submission, and that the directory include appropriate security measures.

Dr. Castellanos: All in favor of that motion?

[Ays]

Dr. Castellanos: Opposed? Are there any other motions? Dr. McAneny?

Dr. McAneny: I'll try to put that rigmarole I said into a motion, but bear with me here. PPAC recommends that CMS clarify exactly which numbers will be eliminated or replaced by the NPI, and which entities will need their own NPIs, such as group practice NPI, IPAs, etc.

Dr. Castellanos: So any discussion on that motion? All in favor?

[Ays]

Dr. Castellanos: Opposed? One thing you didn't say is how often are we going to have to renew this number?

Ms. Brandt: Well, right at the moment, once you get an NPI, Charlie?

Charlie: Yes, the only requirement is that if any information changes, you notify us within 30 days.

Ms. Brandt: Other than that it should last as long as you last. [laughter]

Dr. Castellanos: We hope that's going to be a long time.

Dr. McAneny: That brings a question to mind. Some sessions ago, when we were first discussing PECOS, the rationale we were given for needing to get everyone is was that they were having difficulty identifying physicians who were either dead or for some other reason no longer practicing and therefore should no longer be submitting bills to Medicare. What is the process that the NPI has to let Medicare know when I'm dead?

Ms. Brandt: That's an excellent question. And one of the things that we have in place is actually a new electronic interchange with the Social Security Administration.

Dr. McAneny: How about that?

Ms. Brandt: So we actually have, in fact, we were doing some testing last week with SSA and that's an excellent point and I should have mentioned it so thank you for bringing it up. But we are cross-referencing our data bases with the SSA database, and SSA are the first people, supposedly to know when someone passes away, because their benefits and any other information stops, and that's where their identity is tied to, Social Security Number. So one of the things that we are working for both NPI and for PECOS is to have it so that we have more of that interchange with the SSA database so that we're able to clean out dead docs. We're also trying to work on ways with states and others so that when state license numbers or other things get revoked, it may impact a provider's ability to bill Medicare, that we have more interaction on that level as well, which helps us. Again, from a fraud and abuse program oversight perspective, which is what I worry about, those are important things that we need to make sure we are keeping up on.

Dr. Hamilton: Now you said the number would stay with us for the rest of our practice, but like other numbers, like the DEA number, we re-up that as we pay our fees periodically. Will we be having to refile information on a periodic basis, or only if we have a change?

Ms. Brandt: Only if you have a change. Only if you decide to stop practice, or if you move the practice or if you change your name, something like that. Those are the instances in which there would be an update. But other than that, the NPI, unlike the DEA or other where you'd have to pay a fee, the NPI, there's no fee, and once you get it, it's there. And it would only be if you have a change in information that you would have to update the file.

Dr. Hamilton: So in the unlikely event that we retire prior to death [laughter], we would be obliged to notify you.

Ms. Brandt: Exactly. But I would assume all of you will practice way til the end.

Dr. Castellanos: Til the bitter end! [laughter]

Dr. Hamilton: That's exactly what I'm afraid of.

Ms. Brandt: It's like the Supreme Court Justices. You just stay til the very end.

Dr. Senagore: So if you have a license in two states, and you drop one, if you pop through the process you don't just get dumped from the system, because you---

Ms. Brandt: As long as you are still practicing, I mean, changes in information like that, you would want to let us know.

Dr. Senagore: But if you're talking about taking feeds from a state—

Ms. Brandt: Yes, and hopefully we'll get to the point where we'd have the feed with the state, so that we would be able to keep up on that. And a lot of people do. A lot of people when they decide that they're tired of practicing up north in the winter all the time and they want to move to the south, that's something where they might get a Florida number instead of a New York one, or something like that.

Dr. Castellanos: Are there any other questions?

Dr. Iglar: What if you retire, and go back into practice?

Ms. Brandt: Then you would just notify us. One of the things we need to look into, but I believe the NPI will just become inactive if you go out, if you say that you retired. Then you would just reactivate it, if you will, when you would come back. So say you take an early retirement and you decide that the life of leisure is not for you, then you come back and you'd be able to reactivate the number, or we just issue a new one if it had been—I think after a certain amount of time, we've got it so that if it's been inactive for X amount of time, then we'd probably discontinue the number, but it would be something where again, it would just be the five to ten minutes instead of putting the information back in to get a new one.

Dr. Iglar: And the two state thing, if it's totally different parts of the country, it would be just the same number?

Ms. Brandt: The NPI would be the same number, it's just your state license numbers that would be different.

Dr. Castellanos: My understanding is anybody that wanted to apply can do this at lunch time today?

Ms. Brandt: Correct. Starting at 12:00, we're hopeful that a couple of you will brave go forth where no PPAC person has gone before [laughter] and I will walk you through step by step how to do it on line and it is hopefully painful—[laughter] pain less, relatively painless, clearly I've been worried about this. My boss said to me I can't believe you're going to go to PPAC and try to enumerate them. And I said well I have absolute faith in this system. He said, I can't believe you're going to go. [laughter].

Dr. Castellanos: I think some of us would like to try to do that.

Ms. Brandt: All right, well thank you very much.

Dr. Castellanos: Kimberly, again, thank you very much. At this time I'd like to digress just a bit from our usual format. Typically we have testimonies presented following completion of all the presentations. Today, however, in order to allow for necessary travel arrangements, and to accommodate a prior commitment, I would like to permit Dr. William Plested, III to take a few minutes of our time before adjourning for lunch. Dr. Plested is eager to present this testimony and therefore requests this concession on the part of the Council members in order to meet his very demanding schedule. On behalf of the AMA, Dr. Plested will present testimonies addressing the Pay for Performance initiatives, Recovery Audits, Part D Prescription Drug Program, and the Competitive Acquisition for Drugs. Dr. Plested?

AMA Testimony

Dr. Plested: Thank you Mr. Chair and thank you for your time. I appreciate that. Mr. Chair, and members of the Council, my name is Bill Plested. I'm immediate pastuer of the board of trustees, the American Medical Association and am a Practicing Thoracic and Cardiovascular Surgeon in Santa Monica, California. The AMA appreciates the opportunity to present our views today on several critical issues affecting the physician community. First, we would also like to welcome to new members to PPAC, Dr. Przyblski, and Dr. Sprang, whom I don't see. Dr. Johnson, we congratulate you on your renewed term on the PPAC. The AMA appreciates all of your commitment to improving Medicare for patients and physicians and the magnitude of that commitment has been well demonstrated within your proceedings thus far this morning. We look forward to working with each of you and with all members of the Council. Turning to the issues at hand, I would first like to update the Council concerning Medicare physician pay-

cuts. The Medicare trustees recently predicted cuts of about 26% over six years. Cuts will begin on January 1, 2006. I remind you that is 222 from today. A recent AMA survey shows that if the projected cuts begin as scheduled in 2006, access for patients will be critically impacted. For example, 38% of physicians plan to decrease the number of new Medicare patients they accept. Half plan to defer the purchase of information technology and a majority will be less likely to participate in Medicare Advantage. And about a quarter plan to close satellite offices and/or discontinue rural outreach services. The AMA is continuing to work with CMS and the Congress to avert these cuts, and ensure a stable, reliable payment system. We certainly appreciate PPAC's ongoing support of this goal, as well as your previous recommendations that CMS take the necessary steps to avert payment cuts and implement a new payment system that keeps up with the cost of practicing medicine.

Next, I'd like to address Pay for Performance. The AMA has been very active in quality improvement initiatives including Pay for Performance, as outlined in our written testimony. For example, we have been involved in the development of category 2 CPT-codes intended to facilitated data collection about the quality of care furnished by physicians. We also participate in the efforts of the ambulatory quality alliance. The AQA recently identified a starter set of AMA convened physician consortium and NCQA ambulatory measures currently under review by the NQF. We also presented to PPAC at its last meeting Pay for Performance principles recently approved by the AMA. We are committed to working with CMS to develop Pay for Performance programs that are both fair and ethical. In doing so, it is important to keep in mind several factors. First, Pay for Performance programs may, may save Medicare money, but not to the Part B side of the program. The reality is that most physician performance measures focus on providing more care to patients, not less. In theory, by better managing potentially costly conditions in the physicians' offices, hospitalization's paid for under Medicare Part A could be prevented or shortened. If this bears out, savings accrued to the Medicare Program if a hospitalization is prevented or to the hospital if it is shortened. At the same time, spending on Part B physician services increase. If Part B spending increases, this would trigger additional physician pay cuts under the SGR. In other words, Pay for Performance and SGR are inconsistent concepts because they will punish the physician community for conscientious participation. In addition, as set forth in the written testimony, a host of other issues should be addressed in developing an effective Pay for Performance program. For example, how should payments

be distributed when more than one physician is involved in a patient's care? Over all, we have to keep in mind that physician practices are vastly different in size and type across the country. One size certainly does not fit all. This is in stark contrast to hospitals, which are similar in type and much fewer in number, which means quality measures can be applied fairly homogenously to hospitals, but certainly not to physician practices.

Now let's turn to the Recovery Audits that you discussed at length earlier. Physicians are extremely concerned about the Recovery Audit demonstration mandated by the MMA. It requires the Secretary of HHS to conduct a demonstration under which recovery audit contractors, or RACs identify Medicare part A or B under payments and over payments, and recoup over payments. We greatly appreciate the strong commitment by CMS staff to implement this demonstration as fairly as possible, as well as their willingness to engage in an ongoing constructive dialog with the AMA toward that end. To help alleviate substantial physician concerns about demonstration, we urge PPAC to recommend that CMS adopt the recommendations listed in our written statement. Most importantly, we urge CMS to continue its emphasis on using the RAC demonstrations to educate providers and physicians and promote accurate billing and payment. It should not be used as a punitive device. Further, we understand the RACs currently plan to focus on Part A. The RACs and CMS should provide appropriate advance notification to the physician community if they shift their focus to Part B. In that event, physicians should retain throughout the demonstration, all of their current appeals rights and existing protections under current law and regulations, including the MMA due process protections. In addition, CMS should ensure that under payments identified by the RACs are referred to the appropriate contractor for payment. Finally, the RAC should exclude review of correct coding levels with respect to the E&M-codes, as CMS has indicated. It has been suggested, however, that the RACs may review E&M services for medical necessity. These two issues, correct coding and medical necessity, are very closely intertwined and cannot be viewed independently. Thus, both should be excluded from the review by the RACs. We caution that allowing the RACs to review E&M services for medical necessity likely will be viewed by physicians as a reversal of CMS's promise to exclude correct coding from review. The AMA is committed to working with CMS and the RACs throughout this demonstration process.

The new Part D Medicare drug benefit will become effective on January 1, 2006. We urge PPAC to recommend that CMS ensure that a broad-based education program is in place to help beneficiaries enroll. A recent Kaiser study showed that 49% of seniors will turn to their physicians for help. This responsibility cannot fall squarely on physicians. We cannot absorb another unfunded mandate, especially on top of expected pay cuts of 26% over the next six years.

Finally I'll turn to the Competitive Acquisition for Drugs, or CAP. This program was intended to provide physicians with an alternative to the newly implemented Average Sales Price, or ASP methodology for payment of physician-administered drugs. If the CAP is to be a viable alternative, it is critical that a number of issues be addressed. This is a program that could put patients at serious risk, if drug orders are not filled in a timely and effective manner. Such instances raise the question of who is liable? If program administrative burdens prevent timely and appropriate medical treatment for a patient. The tremendous administrative burden that the program places on the physicians is (1) not reimbursed by Medicare, and (2) at odds with the intent of the regulatory simplification benefits of the MMA. With regard to specific recommendations to the CAP program, the AMA urges CMS to require vendors to offer all drugs that physicians have not been able to purchase at 106% of ASP. We ask PPAC to recommend that the CMS adopt this requirement. We also urge CMS to monitor the CAP program for patient access problems. For example, physicians often waive co-payments for physicians who are unable to pay. Under the CAP Program, vendors may not be willing to do the same. We urge PPAC to recommend that CMS lay out a process for protecting these patients and then to monitor it closely. Finally, we have included in our written statement, other recommendations on the CAP that are too numerous to repeat at this time. They relate to many areas of the program, including, for example, payment for administrative costs, dispute resolutions, categories of drugs to be included in the CAP, vendors obligations to fill orders, timely deliveries and emergencies, disposition of unused drugs, product quality and integrity, and many other aspects of the CAP. We must remember that the CAP is an untested program that will strongly affect drug availability, patient access, and site of service issues. More importantly, it will impact physician administration of in-office drugs to patients who are very ill. Thus it is important that the details of this program are carefully considered and monitored. Accordingly, we ask PPAC to urge CMS to adopt the CAP recommendations in our written statement.

Again, I thank you for this opportunity to present the feelings of the AMA on this issue and I am happy to answer any questions that you might have.

Dr. Castellanos: Are there any questions from the Council? Dr. Plested again, we thank you very much for your very judicious comments.

Dr. Plested: Thank you, Mr. Chair.

Dr. Castellanos: Now it's time for lunch and we're going to resume around 1:15, at which time, we'll have swearing in of our new members. Dr. Joe Johnson is not new but is reappointed and Dr. Greg Przyblski is our new member. Dr. Leroy Sprang is not here today. So see you all back here, why don't we say 1:00, or 1:15. 1:15.

Lunch

Swearing In of New PPAC Members

(not included herein)

Part D Prescription Drug Program

Dr. Castellanos: Next presentation is Part D. Prescription Drug Program. We're certainly interested in hearing what our next speaker has to share regarding the Part D Prescription Drug Program. You're not going to find a copy of a PowerPoint Presentation in your briefing books for this topic, however, Dr. Jeffrey Kelmam, Medical Office in the Center for Beneficiaries Choice in the Centers for Medicare and Medicaid Services is prepared to advise us on the progress of this exciting and innovative program. Welcome, Dr. Kelmam, and thank you for taking time out of your busy schedule to address our Council.

Dr. Kelman: Thank you. Thank you for the invitation. What I thought I'd do rather than a PowerPoint Presentation, because we actually don't have one [laughter] of the level for this professional group, to be honest, is go over the benefits, go over the formularies, go over protection against discrimination. I wanted to touch on risk adjustment, long-term care, and get the three areas that I'd like some input on. Hopefully we can get some of that done in any event. Most of you have heard about the Part D Benefit, which is going to start in January 2006. Basically, the government is going to contract with independent contractors called PDP, Prescription Drug Plans, or if they're within a Medicare Advantage organization, MAPDs to effectuate this policy. There will be bids. Premiums will be based on the bids off a

national benchmark and there will be a standard benefit that will paid from these bids. This will be a voluntary program, with the few exceptions which I'll go over shortly. And the premiums are expected to run between $25 and $35 a month, and within that premium, there is a very specific and somewhat complicated benefit structure. There is a $250 deductible. There is a coverage period between $250 and $2250, which has an actuarial equivalent of 25-75% cost-share, where the enrollee, the patient pays 25%. There is then a gap in coverage up to $3600 out of pocket, at which point, a catastrophic benefit clicks in, where the beneficiary is responsible for 5%. In one way of looking at it, this is really three benefits, three programs into one. There's the standard benefit in the coverage period, which is for most people. There is then a very specific low-income subsidy piece. Now, the one interesting byway in this is that starting January 1, 2006, Medicaid will no longer be covering drugs for seniors. For the full-benefit duel eligibles, and that's about 6 and a half million people, they will shift completely to Medicare Part D. For that group, there are basically no premiums, no deductible, the minimus co-pay of $1, $3, for generic and nongeneric, no gap and no cost whatsoever in the catastrophic period. There's another group, and this is also an important group. The low-income subsidy individuals who are not full benefit duel eligible. That refers to individuals who are 100 to 150% federal poverty level. Now, they get a very complete benefit. Minimal premiums, minimal deductible, very small co-payments, $3, $5, no gap and no cost in catastrophic. The problem is that while the first group, the full benefit duel eligibles will be auto-enrolled, starting or ending October 15th of this year, the low-income subsidy individuals have to make an affirmative action to enroll. This is a complete benefit, minimal cost, but unless they act, and know how to act, it's an application to the Social Security Administration basically. They won't get the benefit. Once they apply if they don't choose a plan, they will be facilitated into one by mid-2006. But this group is a very high focus on because nobody wants them on miss what's basically a completely benefit. That doesn't exist today. The third part is the catastrophic benefit, which exists for everybody, where after $3600 total out of pocket, the beneficiaries responsibility falls to 5%, except in the low income group we're at zero. So we're talking really about three programs, which, put together, are actually quite effective. Auto-enrollment and we're hoping that nobody falls through the gap. We have safety mechanisms in place. Low-income subsidy, which is for those who are not full benefit, have to make an affirmative decision and have a complete benefit, and then everyone else, we encourage everyone else to apply, but it's going to be on a voluntary basis, and based on their own

view as Part D as insurance. If someone chooses not to enroll in Part D, voluntarily, when the program begins, or when they turn 65 in future years, there is a penalty based on how many months they're not in the program. If that beneficiary is currently getting so-called creditable drug coverage, similar to Part D or more, then the penalty is waived when they give it up. So the penalty applies to people who have no insurance now. Because this is not just a payment system, it's an insurance system, we actually encourage everybody to sign up. In the long run, it's clearly actually advantageous for them.

Formularies. It's a big issue. Everybody's talking about it, especially when the USP guidelines came out. Discussion of the formulary first centered on the USP, which was contracted to create a model structure. And they did so and they published it and it involves categories and classes, and at each class has to have at least 2 drugs available. It's very important to remind people that this is actually a structure to compare formularies, it's not a formulary. And it's a floor, not a ceiling. We are currently going over, reviewing formularies as they're being submitted. In addition to the USP guidelines, we're looking at key drug types, commonly used drugs, and 6 classes of drugs of special concern, which are important to clinicians, because in those classes, basically all drugs will have to be available. Those classes are anti-depressants, anti-psychotics, anti-convulsants, which include a lot of the mood stabilizers, it includes immunosuppressants, chemo-therapy and anti-HIV drugs. And within those classes, the PDPs will have to supply basically all the drugs, it's not a matter of formulary restrictions. Now we're allowing tiers within the formularies. Cost-sharing tiers. These are of course irrelevant on low-income subsidies, since they pay the minimus payments, but even in the tiering system, the benefit has to be 25-75% actuarially equivalent, and there has to be a mechanism for appeals from the high-cost and low-cost tier. This is something which by the way doesn't exist in commercial formularies. We're also allowing tiering and exception and off-formulary appeals. The basic rule is all medically necessary drugs that are approved by the FDA, with certain exceptions, which I'll touch on, because it comes important, have to be available. If a drug isn't on a formulary, a patient has the right to appeal, preferably with a physician's help, to get it on formulary based on medical necessity. This is very important toward the rare drug organizations because if there is only one drug to treat a disease, it basically has to be available. It can't be kept off. The question comes up often, will Part D only pay for FDA-approved indications? And the answer is no. It will clearly pay for a drug that has an FDA-approved indication. If an indication for that drug is found on any of the major compendia:

USPDI, AHFS, Drugdex, and Drug Evaluations, it also has to be available. Similarly, if any manifestation of the disease appears on any of the compendia, it has to be available. And last, if there's published evidence for a drug use, that can be used as part of the appeals and exceptions process. Physicians are going to need to get involved with this as well. Discrimination. We went to a lot of trouble to make sure that nobody was discriminated against on formulary or based on the benefit. The formularies and the plans will be compared to other plans in their region. They'll be compared to other formularies in their region. They'll be compared to commercial formularies and they'll be compared internally. We're using disease groupings—3650 ICD9 codes have been condensed down to I think now 85 drug, hierarchical condition categories, which basically cover all chronic disease states, and if a formulary discriminates against any one of those states, or in fact any disease group, it's reason for disapproval. So complicated mechanisms, but no one will be able to disfavor a disease in order to redirect sick patients away from that plan.

We also put in a very complicated risk adjustment. I mean I'm sure you're familiar with AB risk adjustment for Medicare Advantage. There's very complicated risk adjustment for Part D to prevent against negative random selection. It's done demographically, age, and sex, and it's also done with these hierarchical condition categories. Someone with HIV, that patient's plan gets much higher payments than somebody who has no drug diseases at all. We went to a lot of trouble to make certain that in fact we favorably risk adjust chronic conditions and so it's not in any plans advantage to try to select a way. We favorably adjust nursing homes and we favorably adjust the poor, but the general conception, which is partly true, that poor people cost more in terms of drugs, in reality they cost more because they have multiple chronic conditions. It's not clear they cost more because they are poor. And we are over-risk adjusting for that group. And the way the benefit is structured, plans that attract low-income subsidy will be positively advantaged. They certainly won't be disadvantaged.

We made a special accommodation to long-term care. In certain ways this was the hardest group to address because we could set tri-care standards for retail access for everybody in the community. The plan has to offer access in retail. It can, in fact they all will, offer mail order access. The retail access has to meet the tri-care standards, which are that 90% are within 2 miles of a formulary in the city, 90% within 5 miles in the suburbs, 70% within 15 miles in the country. This is clearly irrelevant in long-term term. People don't go out to their local pharmacy. So for the 1.6 million bennies in nursing homes, we set

different access standards. The plans will have to contract to deliver to every nursing home in their region to meet certain performance and service criteria, basically packaging, delivery, urgent access, urgent care, pharmacist on-call, and disposal, if they want to be in the benefit. And they're contracting with either current long-term care pharmacy providers, or new entities that can provide these services, and the bottom line being every plan will have to supply every nursing home that has residents. There is no exception to this whatsoever. Say that—and there may be some questions after this, this is a lot of information—is there are three issues which we would like input on. One is what do we have to do to communicate to physicians? Professional communication so they understand the benefit. Second is what do we have to do to communicate to physicians so they can explain the benefit to their patients. In general, the doctor is going to be the first port of call for somebody who doesn't understand the benefit, and the pharmacist is going to be the second port of call. And the last, and it's a year one issue, but it's important because this is year one, is what steps can we take to get physicians to transition their patients to new formularies before January 1st? I mean the last thing anybody wants if 40 million people filing exceptions and appeals on January 1st, 2006 at the same time. The microcosm of this is the nursing home industry, where we're trying to get the nursing home associations to help us transition these specific residents to new formularies. Last week in December, because they have no leeway. In theory, a community patient has some leeway in filling a prescription. In the nursing homes, there is no leeway. The nursing home reform act requires that the drug be delivered January 1st, as written, whether or not it's on the new formulary. But as a general concept, it would be nice to get cooperation to move people to new formularies before January to prevent a tremendous front-loaded problem in the new year. Thank you.

Dr. Castellanos: Dr. Urata?

Dr. Urata: You can't, it all has to happen on January 1st? You can't do a little bit here, a little bit there? Different segments here, different segments there? It's, what do you call, transition in slowly? Because this is going to be a major problem I think. Especially for nursing homes.

Dr. Kelman: The law actually starts January 1. We're putting in transition requirements for certain transition plans, where there are 30- or 60-day first fill in year one to get over that. But on the other end, what we'd like it to try to transition as many people earlier to avoid going to transition plans if we can, but you're right, it's a big thing.

Dr. Urata: Yes, because the nursing home that I have my patients in, they will have to figure out what pharmacy they're going to use. I mean, it's conceivable that they'll have to change pharmacies. So how are they going to figure that out?

Dr. Kelman: Starting in October, they're going to get information about which pharmacies are in which pharmacies are in which residence networks, and they'll be able to consolidate them down, get the new formularies, so in December, they presumably can change over. It's a big thing.

Dr. Urata: So in December, around Christmas, I should go to the nursing home and write a bunch of new prescriptions.

Dr. Kelman: Right.

Dr. Urata: [laughter] Christmas Eve.

Dr. Kelman: Basically. Christmas Eve. That's what we're shooting for. You got it.

Dr. Castellanos: Any other questions? Dr. Azocar, Jose?

Dr. Azocar: Maybe it will help if we can get some kind of a graphics enhance our understanding of the three categories, a little bit more.

Dr. Kelman: We can get toolkits, which we're preparing on a professional level, specifically to explain the benefit. And we have CDs as well.

Dr. Azocar: I see. And the other question is so far, about what percentage of the [?] have shown the desire to participate? Could you say it's an active thing, people have to…

Dr. Kelman: Some of the projections we've been getting from the industry, from Wall Street, from the PBMs is that in year one, they're expecting 26 to 29 million people.

??: Let's go back to PECOS! That's a little easier!

Dr. Hamilton: Let me just clarify one thing. I was a little slow in writing this down. The 25 to 75% split begins at $250. And it goes up to what?

Dr. Kelman: $2,250.

Dr. Hamilton: $2,250.

Dr. Kelman: And then there's no payment for the non low-income until $36—

Dr. Hamilton: The gap is from $2250 to $3600.

Dr. Kelman: Well, to $5100. It's $3600 out of pocket. Now for the full-benefit duels, and the low income subsidy individuals, there's no gap, and in fact there's not a 25-75 cost share, obviously.

Dr. Hamilton: Now, the effectiveness of this program is largely from a medical perspective, is largely going to depend on how one defines the word "class" because if you have to have two drugs in each class, what is a class?

Dr. Kelman: It turns out, actually, that's probably not going to be the case. I've been looking at all the formularies myself. The class category distinction is basically a floor. We're seeing much more robust formularies. They're looking like commercial formularies.

Dr. Hamilton: Well, this is a critical distinction, because if you define class as anti-hypertensive drugs, and you can have two.

Dr. Kelman: That's right. Classes, as they're defined for this purpose as basically pharmacologic agent class, AC-inhibitors, SSNRIs,

Dr. Hamilton: That is a critical distinction. And the first round of information that came out to the specialty societies was exactly the opposite of what you just said.

Dr. Kelman: I know it was terrible information. This class is being defined very granularly. Stattens, for example, are a class. Now interestingly enough is that I expected to see two or three stattens. Turns out there are more stattens and the reason is that people on a statten, when they choose their plan are going to look to make sure that their statten is on the formulary. If you have two stattens, I think there are now 10 available, you may get 20% people sign up. If you have 10 stattens, you may get 100%, at least on that class. So for marketing rather than structural reasons, we're seeing more robust formularies than we expected.

Dr. Hamilton: And there are probably four or five or maybe six different anti-hyperlipidemic drugs.

Dr. Kelman: Absolutely.

Dr. Hamilton: So that would be—that is a critical distinction. Obviously, I'm delighted to hear you, that you—

Dr. Kelman: There is one other thing. There are certain excluded drugs. Now these drugs were excluded by law and some of them are more or less obvious—cosmetic drugs, weight loss drugs, weight

gain drugs, but barbiturates and benzodiazepines are absolutely excluded. And it was very hard, and we looked on how to get them back in the benefit, and it turns out there is no way. Not without new law. They're excluded for various reasons, and you'll have to ask your Congressman to get the real rationale, but part of it was when they appeared on the Beers list, they became favorites of almost no one, so the sedative hypnotics, that have to appear, in the formularies are things like Zoldopin, Ambien, Lunesta, Sonada, the other anti-seizure drugs. But barbiturates and diazepines are going to be off. Now for the duel eligibles, the states can of course still pay for it. And remember these are basically off patent, they're very cheap. But if the states don't pay for it, and it's up to a state-by-state decision, we haven't found out yet, then they'll have to be a switch to equivalent non-benzodiazepine drugs for the formularies.

Dr. Urata: Are hospice formulary part of this, too?

Dr. Kelman: If somebody executes their hospice benefit, and really is a Part A hospice patient, then they don't come under Part D, they'd get the drugs through a hospice. Just like Part A in the nursing home doesn't come under this either.

Dr. Powers: First of all, I want to thank you very much for clarifying things that we've been so worried about for so long and haven't had a final answer on. First of all, thank you for including anti-epileptic drugs as one of that broader category. Thank you for telling us that off-label drugs may be used. We've been waiting for that. Thank you very much for telling us that, and thank you for telling us about the discrimination policies, because we were so worried that our patients with very expensive drugs were going to be eliminated from all the formularies so I'm glad to hear that. One other question about the barbiturates and the benzos, those are anti-epileptic drugs—well, there's one benzo and two barbiturates that are anti-epileptic drugs and I take that they're off formulary?

Dr. Kelman: This was decided on before we ever saw the Bill. They're off formulary.

Dr. Senagore: Even Phenobarbital? For seizures?

Dr. Kelman: It's off formulary.

Dr. Powers: It's cheap.

Dr. Kelman: It's cheap, now we went through and that of interest, would anybody like to guess how much was the entire cost in the US for benzodiazepines and all barbiturates for full-benefit duel eligibles last year? It was 136 million total. Half of that of course was paid by the federal government—this

was Medicaid, and federal financial participation. It's very very little per state. And so what we're hoping is that the states will continue to support them and supply these drugs. For a private pay individual, it's not really important. It's pennies almost, per pill. But for the duel-eligibles, it is an issue. And we did bring it up.

Dr. Powers: When are we going to get these formularies? When are we—

Dr. Kelman: The formularies are coming in to us now. They will be available on the web probably October.

Dr. Powers: And how many, total?

Dr. Kelman: I can't tell you. But there will be, the rule was that there had to be at least 2 plans per region to avoid a fall back. And there are many more than that. But remember, the interest will be in the regional plans. Nobody here is going to care necessarily about formularies in Alaska, if they're not living in Alaska, and all people in Alaska are worried about formularies in Alaska. [laughter]

Dr. Urata: I live in Alaska.

Dr. Kelman: Well then you'll worry about the formularies in Alaska. So there are a lot of plans available. I loved Alaska when I was there by the way. [laughter]

Dr. Urata: I'm glad you said that.

Dr. Kelman: I also loved Hawaii, too, but I figured somebody might be from Hawaii…

Dr. Urata: You're doing a good job of recovery.

Dr. Kelman: That's right. But the number of plans per region is the key.

Dr. Powers: Because our patients are going to ask us the specific plans, actually. They'll say which plans have my drugs on it. Some of them don't know how to look things up.

Dr. Kelman: Absolutely and they'll be on the web and they'll be physical versions as well.

Dr. O'Shea: This is the crux of my problem because I can compartmentalize it into two places. Your first thing when you were talking about a, b, and c, or 1, 2, and 3. You have to always look at those like I'm going to be a CPA to my patient, if you have this and you have this, and you know what? I want to just say that's not where my interest is as a physician. The formulary, what's appropriate for my patient, that interests me very much. So I just want to say if I can that I really want a lot of information, very digestible. I don't care if you give them Happy Meal little dolls that say a, b, and c, something that's very

easy, for them to understand. Something that really can be picked up very easily. Because I do not want to take my time out of my time to do medicine with my patient into telling them, well let me see your tax return, or let me see your card. So my next point is, we do need to get the formulary, we need to have input on the formulary, and know what kind of choices we have because to me that's really interesting, but my patients are going to come with the other questions and [sound interruption]. What I've heard is that pharmacists are going to ask to be reimbursed for giving some of this advice to patients. They're actually going to want to code for it. We don't have enough Medicare dollars to do that. I don't see why it has to come out of the Medicare benefit for a pharmacist to give that. And yet, if I put myself in their shoes, I am going to have a lot of patient time on giving them advice on this one. So that's why I preface it with I want a lot of information, usable information, repetitive information, in your face kind of information to the patients to learn about this. So that they have more than enough to know, and have access to. And is it going to be on there, Dr. Kelman, see your physician about this? Because I really want to know how much responsibility you're going to give to physicians to be educators and CPAs.

Dr. Kelman: The pharmacists, I'm sure you've heard something about the Medication Therapy Management Programs, which I didn't even touch because it's a whole nother talk, but in the Act, the plans will have to do Medication Therapy Management for specific groups of patients. The ones that have multiple co-morbidities, that have projected high costs, and have poly-pharmacy. Now the plans can pay for it and administer it anyway they want, as long as it fits our general criteria. And in year one, we're being very liberal of it. The pharmacist would like to be able to deliver and charge the plans, not Medicare, for this service at the pharmacy counter. Nursing homes would like to do it in the Nursing home. Senior housing the same way. And so that's the payment that you've probably heard about. And yes, we're trying to make material available as simple as possible. And the a, b, and c category was actually more for this group than for the clients. The duels will be auto-enrolled. They won't have to know anything. The low-income subsidy will fill out a form that will go to Social Security, and they will get the full benefit and everybody else is the remainder of the plans.

Dr. McAneny: Couple questions come up. One is that I know what my patients do with forms that they're given to fill out. They bring them into the office and hand them to me, and go Dr., could you please fill this out for me? So please make those simple, because I agree with Gerry, we don't have a lot of extra

time to do it. One of the things that I would need that would help me select which plan is going to be the best for my patients is a computer program where I can type in the 25 drugs that they take, I'm exaggerating but not a lot, and then you can look at them and say, you can crosslink them with the plans and say which ones are on which plans. That's really what I need to be able to do in the office. And I won't be doing it myself. I'll be basically hiring somebody to do this. So please be aware that what happens in a lot of practices is going to be that—I would rather pay a mid-level person to do that than I would have my doctors not generating E&M-codes and bringing in income to the practice for that time period.

Dr. Kelman: I agree. We're working on an application just for that. The formularies and the information will be on Medicare Compare, but we'd like an application, I got down to translate a list of drugs into the formularies that are closest. The good news is that many, if not most of these formularies are very repetitive. I mean they all have the stattens, they all the ac inhibitors, they all have all the anti-psychotics, all those other drugs, anti-depressants, so people in mental health are going to be basically covered no matter which formulary they're on. And for the rare diseases, all drugs will have to be available in any event. But yes we are looking for an application.

Dr. Hamilton: I just wanted to ask 2 other questions. One has to do with this education that we've been hearing about. What sort of plans does CMS have for educating Medicare beneficiaries in general about this program? And what sort of requirements will you have that the specific plans provide education material for their customers or prospective customers?

Dr. Kelman: We're going through a massive at least massive to me outreach in education program. We have a whole division that's doing nothing but Part D outreach. And it's supposed to be with the pharmacists, long-term care, senior housing, adult day care, in our ten regions there is a Part D contact person and lead in each. It's being multiple media, it's coming from CMS so for mailings. Hopefully it will be enough. My general experience with this group is that they may not respond to mailings, but they do much better with direct face to face conversion. And we're trying to arrange not only to have all the Social Security field offices do it, but to have subcenters, places like adult daycare. We have a partnership arrangement just completed with NADSC as well as ASL, Assisted Living groups to provide information to their local communities on Part D. But you're right. It's a tremendous effort. Because this is a completely new benefit.

Dr. Hamilton: But CMS will then be providing information to pharmacists and to physicians offices that we can then pass out when they call—

Dr. Kelman: We have two forms that, we have posters. We have the government printing offices working all night. They tell me, just to get the stuff out.

Dr. Hamilton: You wouldn't expect CMS to be responsible for each of the however many plans there may be. Will you require the plans themselves to provide information specifically related to their plan or what?

Dr. Kelman: Absolutely. They have to file, with the application before the contract is signed, file in use statements about all their marketing materials. And it has to be accurate. No plan would be foolish enough not to make them accurate, because they brush into real issues.

Dr. Hamilton: OK, well the second question I have is that the FDA recognizes certain drugs as having a narrow therapeutic index, which means different things to different specialists, but for example, in neurology, some people feel that Dylantin works very differently than the generic form. Cardiologists or other internists feel that Coumadin and Warfarin are somewhat different, and this applies to other types of drugs. Will the formularies take into account these narrow therapeutic index, or NTI drugs that the FDA recognizes.

Dr. Kelman: We're trying to encouraging generic exchange is obviously on everybody's menu right now, because it's a way of saving money. On the other hand, for the ones for the therapeutic index that's accepted—there is a provision for an exceptions process to bring that drug back into the formulary, if the physician feels it's important. Basically every drug except for the excluded drugs, has to be available if it's FDA approved in this country. Now if there is a drug that's not yet FDA approved here, it won't be on Part D. But that's a rare thing. But every FDA approved drug has to be available with some mechanism or other. And for the appeals and exceptions process, and I'm sure all of you have dealt with an appeal, in a commercial formulary, you go to the commercial formulary and you float up to the top and the appeal is decided. And in this case, the final appeal comes here. It's done by CMS and then administrative law judge. In certain ways, much better protection for the individual and the doctor, because it's not the plan who decides.

Dr. Hamilton: Thank you very much.

Dr. Castellanos: Are there any other questions? Dr. McAneny?

Dr. McAneny: Yes, I would like a little more information on your tiering of pharmacy benefits. And the reason that I ask this is that we start to see among some of the private payers a tiering of first of all the generics versus acceptable, i.e., cheap brand name drugs, and then there's the less cheap, and therefore they're a third tier and a higher co-pay. And what we're starting to see now is that some pharmacy benefit managers are sticking in a 4th tier, which they call biologicals, or bio-tech drugs, whatever that means, and then they charge fairly absorbitant co-pays. And as far as I can say what that means is it's chemotherapy and anything expensive. And I'm concerned about that because if you're going to make a patient pay a huge co-pay on a drug, they can live without their Botox, but it's hard to live without their chemo therapy, so I'm concerned that for the oral chemo drugs which may not be particularly inexpensive, whether or not these tierings are going to avoid discriminating against that set of patients.

Dr. Kelman: Very good question. And for, we see, we expect to see four tiers: the generic, the preferred, the non-preferred brand, and in some cases, a so-called specialty tier, which is exactly what you talked about, the high-cost biologics. On the other hand, there are two really large protections for the patients. One is the total benefit has to be 75 25. So a tier that's very high will make the benefit itself illegal. It'll be rejected. We're not expecting, generally speaking, we're limiting the highest tier, the specialty tier, to either 25% or their preferred, the second-tier drug, which in most cases is always going to be less than 25% so I don't expect to see a specialty tier of more than 25%. In addition for this class of drug, and this by the way is raw data you're getting, or it's just released this morning, is the benefit protects the high-cost patients at a level that in fact lower cost drugs don't because of the catastrophic. For the expensive, HIV, chemotherapy, the patients will go into their catastrophic benefit by the 3rd or 4th month. And then it'll be a 5% co-pay. The way the benefit is written, with $3600 out of pocket, for the high cost biologics, it's a very very good benefit. Because in the second quarter of the year, they're into their 5% catastrophic co-pay.

Dr. Castellanos: I have a question really to CMS. I know CMS went to MedPak complaining about peaks in services, especially program expenditures for Part B. And especially when you're setting a target for Part B. I can see in December and January and February a tremendous [interruption]. And I hope you recognize that, and I hope you recognize that this is necessary for this is when the patients (1) get their

prescriptions filled, and (2) probably see those patients in follow up to see how they're doing on the new formulary drug. Any comments on that?

Mr. Kuhn: Well, we're going to have the Office of the Actuary—we're already looking at these and trying to do some estimates now in terms of how that might impact. But also there are, and we're looking at what the statutory authority has in terms of new mandates and how that has impacted [interruption] SGR calculations. So we are looking into that.

Dr. Castellanos: Because that's going to be a serious problem. And I guess my last comment is a comment you've heard from everybody. Basically what you're doing is putting the burden on the physician and his office, office staff, the office managers, the billing and the RNs to really educate the Medicare recipient. And we've heard statistics this morning saying that, from AMA, that up to 49 to 50% plan to go to their physician for this health. Yet this is another unfunded mandate. And I understand where you're coming from, but I certainly hope you can understand where the practicing physician is coming from.

Dr. Kelman: I absolutely can, and the pharmacists tell me the same thing. And the long-term care stations tell me the same thing, and by the way, I think they're all right. As are you.

Dr. Urata: This is a different comment—unless somebody else wants to comment on the last thing? When you have your formularies, how often are you going to [interrupted]

Dr. Kelman: Well, they'll be renewed—

Dr. Urata: Is it like a yearly rotation or is it—

Dr. Kelman: They'll be automatically renewed at every new benefit year. If new drugs come into the market, then they have to be accommodated on a mid-year basis. If a plan wants to change a formulary in mid year, they have to give us 60 days notification and approval and then give a 60-day notification to the beneficiary before the change is affected.

Dr. Urata: Example I had with a problem with a too-frequent renewals is our state just started Medicaid—

Dr. Kelman: PPO.

Dr. Urata: Program. And for six months I had a patient on Cozar, and then the formulary changed and Benecar became the arb of choice, and so in six months I change my patient back to Benecar, had to follow the patient to see for changes, and then six months later, they switched back to Cozar again. So I got

on the phone and talked to the people about it. I said this is ludicrous. This is a heart patient, that's taking, switching in mid-year. And so I hope nothing like that happens.

Dr. Kelman: No, we're discouraging mid-year changes in—except for new drugs coming on the market.

Dr. Castellanos: Are there any other—Dr. Powers.

Dr. Powers: This is on the lighter side. I have an idea of how you can market this to the patients and the people. Pick the top three TV dramas, and have a character going through it [laughter] and make it reality TV show.

Dr. McAneny: Desperate *Senior* Housewives. [laughter]

Dr. Kelman: I'll float that up.

Dr. Castellanos: Are there any recommendations that PPAC wants to make at this time? Dr. McAneny?

Dr. McAneny: I'll try to handle one. PPAC recommends that CMS request a pharmacy benefit management planning code with new money be developed to pay physicians for helping patients navigate the new benefit. Put it through the RUC, do the whole thing.

Dr. Castellanos: Is there any discussion on that? Dana, do you want to read that back to us?

Ms. Trevas: Do you want to define "new money?" [laughter]

Dr. McAneny: Not budget neutral and not lowering all the other codes, the way budget neutrality works.

Ms. Trevas: PPAC requests that CMS request from—from whom?

[chatter]

[interruption]

Ms. Trevas: PPAC recommends that CMS request from the AMA CPT Editorial Panel a pharmacy benefit management planning code that is not budget neutral, be developed to help physicians help patients navigate the new pharmacy benefit.

Dr. McAneny: To pay physicians for helping patients.

Ms. Trevas: Yes, you're right.

Dr. Senagore: Although it's laudable gold structurally, it's kind of difficult because you're going to have to have a specialty society bring it forth to CPT. Unless your society wants to bring it forward. That would be how I would have to go. I would underline budget neutrality above and beyond, if it gets that far. Someone like that would have to bring it to CPT. That would be the first step.

Dr. Castellanos: One more time, Dana could you read that back, please?

Ms. Trevas: PPAC recommends that CMS request from the AMA CPT Editorial Panel a pharmacy benefit management planning code that is not budget neutral be developed to pay physicians to help patients navigate the new pharmacy benefit.

Dr. Castellanos: Any further discussion? Dr. Senagore?

Dr. Senagore: Friendly amendment? Could it be reworded that should a CPT-code be approved for whatever that was described as, that it be, whatever the terminology is for budget neutral, however that goes? I would just start out with: Should a CPT-code be approved for X, whatever the terminology was, then it will be—

Dr. McAneny: CMS will pay for it with non-budget neutral money.

Dr. Przyblski: Not to be a nay sayer, but in the sense, there is a system that it helps for that time. In our E&M-codes, part of our coding level is based on the degree of counseling and coordinating care as opposed to your documentation requirements. And does this not fall, still, within the purview of what we're supposed to do as physicians. And you can actually code a higher level to do that.

Dr. McAneny: If you can code a higher level to do that. The problem is what we traditionally do is talk to patients about their drugs, the risks and benefit of a given drug, the interactions with the other given drugs and what the thing is, we don't usually sit down with patients and say now you've go this much money, so you're going to have to pay this much, and do all that economic stuff. That doesn't really—

Dr. Urata: I don't think we have to do that. We might a little bit, but we'll have to do is say because you're in this category, you should go with this firm or the other firm for your drugs, because—am I correct?

Dr. Kelman: Basically. The position—

Dr. Urata: I mean Social Security is going to determine what category they go into.

Dr. Kelman: Ecnomically. You don't have to do that, but you will have—it's that pharmacy list.

Dr. Urata: We're picking the formulary. Which company who has which formulary, then he's going get it on a web page, so you can just have your computer right there and just push the correct button.

Dr. McAneny: I'll send all mine to you.

Dr. Castellanos: So we do have a motion on the floor. Dana one more time, I'm sorry.

Ms. Trevas: PPAC recommends that CMS request from the AMA CPT Editorial Panel a pharmacy benefit management planning code be developed to pay physicians to help patients navigate the new pharmacy benefit. Should such a CPT-code be approved, PPAC recommends that it be exempt from budget neutrality.

Dr. Castellanos: Is there any further discussion?

Dr. Przyblski: I hate to do this again, but just putting on my RUC hat, I'm trying to see how this is going to get surveyed where you have absolutely no information on what the work's going to be like, what the extent of it is. There are certainly a learning curve to this where at the beginning, it's going to be onerous and when you do it a few times it's going to be easy. I don't know how you'd measure it.

Dr. McAneny: Yes. So it's not practical.

Dr. Przyblski: I think it's a laudable request that you have. I don't know how practically you would be able to do it.

Dr. McAneny: Hmm.

Dr. Castellanos: Any other comments. I'll call the question. All in favor? Opposed.

[Ays]

Dr. Castellanos: We better have a hand count, OK? All those that are in favor, could they raise their hand? One, two, three, four, five? All those opposed, one, two, three, four, five. I guess the chair does have an opportunity! [laughter] And I would be against that motion.

Dr. McAneny: OK.

Dr. Castellanos: Dr. Kelman, I have one other recommendation is that PPAC asks that at the next PPAC meeting if you could provide us with whatever information you have that is current at that time, to include the education material, any information on formulas, etc. If that could be available to us at our next meeting. Is there any discussion at that? Call the question. All in favor?

[Ays]

Dr. Castellanos: Opposed?

Dr. Senagore: Would this be something that would fall under the requirements for radio and television station [interrupted] announcements and I mean, would that be another vehicle?

Dr. Kelman: We're doing a lot of local TV. It is big, you're absolutely right.

Mr. Kuhn: It's probably the single largest product launch that you'll ever see. And we're really doing [interrupted]

[chatter]

Dr. Castellanos: Dr. Kelman we certainly appreciate the informative presentation and we'll look forward to—I'm sorry, excuse me.

Dr. Hamilton: I'm not sure [interrupted]. I would really like for us to for PPAC to urge CMS to work with the AMA and with primary care specialty organizations and with pharmacist groups to develop information for Medicare beneficiaries that explains the program, and make this available through the physicians' offices and pharmacists.

Dr. Castellanos: You're making that as a motion?

Dr. Hamilton: I'll make that as a motion.

Dr. Kelman: You may want to—I hate to interrupt. I don't have a place here. But you may want to wait to see what we have. Because we have in theory from my point of view, extensive materials from the pharmacists group and from Impact.

Dr. Hamilton: Well, I just think when you get this stuff together you need to run it by the people that are going to have to be handing it out.

Dr. Kelman: This will be a very useful group to run it by. When is your next meeting?

Dr. Castellanos: August 22nd.

Dr. Kelman: We can certainly have it before then

Dr. Castellanos: Any other discussion? Dr. Kelman, thank you. As you can see there's a lot of interest. Keeping on schedule, it seems like drugs are the topic right now. We're going to be talking about competitive acquisition for drugs. We now continue our presentation with the most up to date information regarding the competitive acquisition for drugs and hopefully news on the publication for the Final Rule. May I introduce Ms. Amy Bassano, newly appointed Director, Division of Ambulatory Services, Centers

for Medicare and Medicaid Services. Prior to joining the Center for Medicare Management in March of 2005, Ms. Bassano worked for four and a half years in the Office of Management and Budget as the lead analyst for both Part B and D. Prior to 2000, she was a Part B issue analyst in the CMS Office of Legislation. It's my pleasure to introduce Ms. Bassano.

Mr. Kaye: Also Terry Kaye

Dr. Castellanos: Terry, I didn't realize it. You're a familiar face and we glad to see you here back also.

Competitive Acquisition for Drugs

Mr. Kaye: Thank you also very much. I'm just going to make a very few brief comments. Actually our whole session today will probably be reasonably brief because as you know, our Final Rule is not out yet, but as far as our time line, we thought that might be at the top of your list of things to talk about. Basically, as you know, the program, this new Competitive Acquisition Program, is effective January 1, 2006. So to make that happen, there are several major milestones along the way. One of them is we published the proposed rule back in March, and we've been saying that we're going to do the Final Rule by the end of May. It's quickly getting to be the end of May, so we're madly working to make that happen. If it doesn't happen exactly by the end of this month, I can assure you that it'll be very soon after. The other major milestones is that we'll be working with vendors to establish contracts for the program this summer, so that by the fall, we'll announce the process for physicians who are interested to enroll via whole sign up process later that we'll announce. Some of the things that Amy's going to do is sort of give a refresher for those of you that are familiar with this new program, and for those of you who are new, she'll be hitting the highlights of the program. We know this was discussed in the last PPAC meeting and that you have a number of recommendations for us, and because of the process, we can't go into the specifics of course, but we can assure you that we very seriously have all gone through the recommendations and we are keeping them closely in mind as we develop the Final Rule. The final message that I'd just to like to give you is that this Competitive Acquisition Program is an alternative the existing program where we pay Part B drugs based on 106% of average sales price. This new competitive program is totally voluntary. So it's not anything that physicians have to do. It's something that's an alternative, and we certainly hope that physicians will consider it. But in the end it is voluntary. So with that, why don't we just go ahead and start.

Ms. Bassano: Thank Terry. I will run you through a little background on CAP. As Terry mentioned, it's part of the two-prong in MMA to change the way Medicare pays for Part B drugs, the first obviously being the ASP system, which went into effect in January 1st of this year, and the second being the Competitive Acquisition Program of January 1st of 2006. And we've published an NPRM back in the winter, and just to refresh your memory on that, we were lots of different issues we were soliciting comment on given the constraints or parameters that were outlined in the law. The first being the potential drug categories. Which drug should we be including in this? Should it be oncology drugs? Some other specialty, rheumatology, gastroenterology, which drugs should they be? There was also a discussion of whether or not it should be all Part B drugs, or just physician injectible drugs and we had some concerns about that, if it were to be the inhalation drugs, since the requirement is that it is required to have the drug administered by the physician and all those, it says Part B drugs, the inhalation drugs are not actually administered by the physician. Then the potential geographic areas and how we were going to phase this in with the competitive areas be on a national basis, on a state basis, on a regional basis. We were soliciting comments on all these areas. On the regions, we threw out the 34 PDP regions for the Part D benefit, but just as a place to start to potentially getting comments. Then how would the competitive bidding process work? We proposed to say that the bids have to be no higher than averages sales price plus 6, and that we'd be then within that area, we'd be having single price per individual drugs. And then what the standards for bidders, who could be a bidder? What sort of vendor would be working with—and we had a couple of proposals there on how they have to acquire the drugs from the manufacturer. They'd have to be licensed to distribute in every state that they are bidding. Their capacity to ship five days a week, and in emergency situations, they would have to be supply their audited financial statements, so we could verify their financial solvency, and also, this would turn out to be one of the most controversial areas is the three years experience distributing Medicare Part B drugs. We also talked about the number of winning bidders we would have, the statute says we can have a minimum of two, we proposed to have no more than five for each of the competitive acquisition areas. The claims processing, we intend to hire designated carrier to process the claims, the local, the administration claims would go through the regular local carrier, but the claims for the CAP drugs would be submitted by a vendor to a particular carrier who we're in the process of hiring, and the drug administration, the law says that we can't pay for the drug claim until there's been

verification that the drug has actually been administered. So we had some standards surrounding that, including the physicians submit their drug administration claim within 14 days of the administration. We were very happy with the comments we received. There were approximately 500 of both paper and electronic comments. They were from a variety of sources from individual physicians from medical specialty societies, potential vendors, pharmaceutical manufacturers and anyone else who is generally interested in the CAP program, and in general, the comments were very useful and we appreciate everyone submitting them because they've been very helpful to us as we try and put together this Final Rule. I can talk a little bit about the types of comments we got and the issues that were brought up.

On the drug categories, the comments did center again around whether to include oncology or not to include oncology and whether, which types of drugs—should it only be oncology, should it be all drugs, should it be all drugs except oncology drugs, and so we have opinions across the spectrum. Seeing would be for the competitive acquisition areas. Many comments were supporting doing this on a national basis, although we did get other comments saying that you should start on a smaller basis, and whether it be a regional or state area. No one really mentioned a particular area that they thought we should start or exactly how we should be drawing their regional lines. So we were interested to be hearing about that. But there was no general consensus on where to go if we were go to on a regional basis. Beneficiary co-insurance was an area of extreme concern from the physician community and from the potential vendor community, although they had different perspectives on it. Potential vendors were very concerned in general about their financial liability, and they saw that having to collect the beneficiary co-insurance as being one of their biggest areas of liability and they were asking for us to do things to help them with that. The physician community on the other hand was suggesting how much credit they've extended to beneficiaries, and how often they have written off the co-insurance for these particular drugs and we're recommending that vendors be allowed to do the same and encourage them to extend the same type of credit over time to beneficiaries to be as flexible to them because these are very expensive drugs and it is possible they may not be able to pay the co-insurance. Another issue was the partial payment of claims We had said we wanted to get thoughts on should we pay the claims partially, since we'd already had this issue? That they could not pay for the drug claim until the drug was administered, should we pay some sort of partial payment for the drug ahead of time? And the vendors were, in general they may not have addressed this

issue. Specifically they were very concerned about their liability, and the time it would take for them to be paid for their drugs. So they wanted to be paid when the drug was shipped, in general, instead of waiting for the drug to be administered. And then, got a lot of comments from physicians and physician specialty societies about the administrative burden that CAP would be for them and the additional paperwork and other requirements that CAP would be imposing on them and how to, what they would need to do in order to be a CAP participating vendor. Some of the other comments we got were how this CAP vendors would have to be licensed, whether they're a wholesaler, distributor, pharmacist, and lots of issues about what the state law is, since we had said you proposed to say you'd be licensed in any of the states you are operating in, exactly what kind of license and what sort of model were we anticipating? And then the physician election process was another area we got some comments about in particular about groups electing in. We had proposed the election would have to be on a group practice basis, and not on individual physician, so all the physicians in a particular group would be in versus just one or several. And then others comments about the definition of an emergency, because the physician in emergency situations is allowed to supply the drug from their own supply and then get restocked by the vendor in case there's an emergency? And so what does mean, how do you define emergency? And when would that be triggered? Lots of other comments on smaller issues as well, about especially operational issues, about how we're going to make this work and what would be necessary and different things we hadn't necessarily proposed in the rule, but I'd have to say again that they were all very useful and we really appreciate the comments because this is a big program and a big change from the way Medicare has operated in the past, so we appreciate all the help we can get in trying to get this program running by January 1st, and we can get successful. Happy to take any questions.

Dr. Castellanos: Thank you. Are there any questions from the Council? Well, I know I do. I spoke to you already Amy about one concern that I have. And it's probably an answer you can't answer for us. Under the MMA, it mandates that the Office of the Inspector General report to Congress by October 1, 2005 on the adequacy of reimbursement rates under the ASP methodology. OIG is required to conduct a study on the ability of physician practices in hematology, hematology oncology, and medical oncology to obtain these drugs and biologic treatments for cancer patients at 106% of ASP. Urology, which I am a member, we provide medical oncology to patients. But we've been excluded from this study, especially in

the face of several of the drugs that we administer we cannot buy for 106% of the ASP. I know there's probably very little you can do. I asked you to look into it, and I was wondering if you have any answer for it.

Ms. Bassano: I did trade some messages with colleagues in the Office of Inspector General and they did say that these were specialties named in the law, so they didn't have much discretion in terms of looking at how specialties are defined. And you're right. It's hematology, then hematology/oncology, and medical oncology. Those were the three specialties that were named in the law, so they didn't have much discretion at looking at that on the particular areas. But to say from the CMS perspective, we're very concerned about the ASP payment rates and adequacy and interested in hearing about circumstances when people are having trouble accessing those particular prices. So any information you could provide us would be useful as we sort of go through and we have some other studies we're doing on large purchasers, and so that would be helpful to us. I'm not sure that there's anything we could do right away to change the payment rates, but we are very interested in talking to different physicians about how they can acquire the different drugs, and what the prices are that they have access to.

Dr. Castellanos: I certainly appreciate your looking into it. Dr. McAneny?

Dr. McAneny: I have a couple of concerns about the CAP Program. One of which is the bias definition. If you have a large purchaser who becomes a CAP vendor and then has the ability to move the market because they can get ASP, or they can get their purchase price to be less than ASP plus 6, which they're going to have to do or they will not stay in business. So they have to get a number that's closer to ASP minus, in order to be able to carry the overhead of a distribution center. Similarly to your concerns about the fact that a physician that has to do an infusion service cannot get the drugs at ASP and stay in the black. So if these vendors in these large corporations can move market to where they're shoving the price their area, it may be exceedingly difficult for anyone else to be able to acquire drugs at ASP therefore it'll make anyone who chooses buy and bill as their option to be able to do it. I'm also very concerned about the small rural provider of oncology services, who often, a lot of oncology services are done in one and two-doctor offices, particularly in rural areas. They don't have a huge volume of patients that they see. About half to 60% of those patients are going to be Medicare patients. So if you push those over into the CAP program, then what you're doing is your taking the remaining buy and bill 40% and you're trying to put the

costs of the infrastructure, chemo mixing hoods that are OCIA compliant, OCN certified nurses, etc. all the stuff that's required to provide an infusion center on to those 40% of those patients who remain on the buy and bill market. When you add on the additional costs of keeping the inventory you can't just look at your shelf and say I've got 10 vials of adromycin that will get me through next week. You have to say, well, these three are for CAP program so that means I only have 7 and you just have to do a lot more inventory juggling, even it's not a new refrigerator. Even if it's the same shelf. It practically cannot be. And it starts to become this huge inventory problem. So you get decreased number of people who are paying for the infrastructure, decreased amount that you can buy the drug for, so that you're losing money on the drug itself, increase inventory prices, and I think what you're going to see very quickly is that people that are doing a little bit of chemotherapy, the one or two doctor offices are going to say forget it. This is not worth the hassle and I can't maintain a safe environment in which to do this. Send them to the hospital, or wherever. Then the hospital's also going to ASP and one of my questions would be is are they also going to be under a CAP program or they can continue to use whatever it is that they buy their medications from. So lots of questions. I do that, I'm sorry.

Ms. Bassano: The last issue was, you were asking about the hospitals.

Dr. McAneny: Well, forget that, that's less important to me. I want to hear what you think will happen to the small oncology providers in rural America.

Ms. Bassano: I would guess, not being oncology provider, that CAP would be a good thing for them if they'd have this option, it's something else. If they can't get CAP at the ASP plus 6 prices or are having a hard time doing it, they won't have to worry about buying the drugs. The vendors would have to be prepared to ship the drugs to no matter how rural an area they are within the time frames. So they would have access to the drugs, and they wouldn't have to, they of course would still be able to bill for the administration of the drugs so they would have that payment for covering their other services.

Dr. McAneny: I guess what I'm telling you is that the payment that is allowed for the administration of the drug is not sufficient to put in the administration infrastructure that allows one to even considering administering the drug. And so if you've taken, if there's more and more people under a CAP program and less and less of your practice is a buy and bill where you have any degree of mark up, you're just not going to be able to afford to keep that inventory. Plus if you're making zero incremental money, on

administering drugs in the office, why should any one- or two-person group bother to keep the liability to maintain all of the extra space, the office rent that you have to have to have the space to do it, why should they bother?

Ms. Bassano: Well, if they're happy under their current situation, there's no reason they have to switch to CAP. CAP might not be the right thing for a physician in that situation. If they're working, if it's working out well for them in their current situation, we don't want to disturb any good situation. CAP is really just an option out there. And if it isn't working so well for them under the current situation, we'd like to think CAP would be a viable option for them. But if anyone is happy the way it is, we don't want to interfere with that.

Dr. McAneny: I'm sorry, I don't mean to be argumentative. But as you develop this CAP situation, and CAP shifts what ASP is determined at, then very quickly, there will be no one in a small situation who can afford not to be in CAP because once the ASP vendors, the CAP vendors can get ASP manipulated through moving market, no one will be able to afford to stay out of it.

Mr. Kuhn: But there is one other option within CAP, too. It's in addition to the drug acquisition. It also deals with the beneficiary co-payments, so that overhead expense that the physician office has with that is also alleved as well, so that might help offset some of the infrastructure build up.

Dr. Senagore: Fortunately, I don't have a dog in flight, so I can be somewhat dispassionate, but [laughter] it seems to me that we've, a system has been created, once again, where the economic relationships are not aligned. In this scenario, isn't the customer vendor relationship the patient, and of the CAP provider? Whereas the physician now is just the intermediary and really not part of an economic transaction.

Ms. Bassano: They wouldn't be sensitive to the cost of drugs at all.

Dr. Senagore: Right, so in that system, then, why is it not constructed that the intermediary is completely outside of the risks of that relationship, whereas the warehousing and inventory management and all those things become the responsibility purely of the vendor of the product and the beneficiary is simply showing up at a site of distribution to access that.

Ms. Bassano: That's the way Congress designed this system. So we don't have much authority in terms of—

Dr. Senagore: I understand but this could be a learning evolutionary process of where I think you need to go, because under the system, you are expecting the physicians will have some burden financially to manage this process, without being able to tap into any of the revenue string.

Dr. McAneny: There's no way that you can get the physician who is administering the drug in a safe environment completely out of the costs of doing that, because the administrative costs of taking a CAP type system, where you have to make sure the right drug is at the right place at the right day for the right patient and making sure that you've submitted the right billing and gathered all the correct data and sent it back to the CAP provider, etc. That, by the way, the law in the proposed rule making, is lands on the physicians. We're the ones who have to administer the drugs to the patients, so there's no way that they can completely get us out of the chain of command of those drugs. If they were to set up a system whereby the patient goes and gets the drug directly from the distributor, there is no way I would ever infuse that drug into a patient because then if I've lost the chain of control of that drug, I don't know if it's sat out in the hot sun in New Mexico in the back of the pick'em up truck, I don't know whether it went through the pharmacy in Kansas City that diluted the Taxol, I don't know whether it's the fake Procit that showed up in Florida. And if you don't have a good chain of control of that drug, I'm not interested in taking any of the liability in my patients for the risk.

Dr. Senagore: What I was suggesting is that it's the vendor's responsibility is to have that product show up at your doorstep. For Tuesday when the patient shows up for their treatment. We do it often in surgical procedures where a device is not covered and it becomes the patient's responsibility to financially cover the acquisition of that device. The hospital can't pay for it, there's no mechanism. We don't pay for it. If the patient desires that device, they pay for it. And actually secure the delivery. We would expect that the device would be sterile, for implantation, and it comes in a process where we're assured of that. But it is outside the system. What I'm wondering from a distance is why is the physician having to take this responsibility for product to show up?

Ms. Bassano: I'm not sure if I understand what you mean—the product to show up, because if the vendor is—

Dr. Senagore: From what Dr.—

Ms. Bassano: The vendor's the one who has to ship the drug, show its pedigree and ensure that it is the product they say it is. So it's just that the vendor has it because they're the ones who prescribed it.

Dr. Senagore: So it's their liability for on-time delivery? Product capability? So…

Dr. McAneny: But the analogous situation would be there is no money anymore in the system to make sure that you have somebody at the door to receive that device when it shows up at the door of the hospital and to know who ordered it and get it to which patient and make sure it truly was sterilized and double check that and there's no overhead built in to take appropriately do whatever billing is necessary to get that patient to pay for that particular item and no overhead money in the system to make sure you had an OR to put it in and nurses hired to help you do it, etc. Because the CAP vendor parks the drug at my doorstep and asserts that it's the right drug for that patient, the inventory costs still are there because I have to manage and store that drug and mix that drug and administer that drug and provide the tubing and make sure the nurse is certified and be there to do all the stuff that go with doing it just like you do if you put in a new device. So my concern with this and my question with this is with the CAP system and perhaps with the full ASP system, with all of the money taken out for the inventory costs of this, and I see the CAP as increasing the inventory costs and decreasing the available money that practitioners will use to run the practice on, that we may eliminate a lot of the infrastructure that's across the country to infuse chemotherapy, particularly in the smaller more vulnerable areas that can't take a tiny margin and make more on volume.

Dr. Castellanos: Any other points that want to be brought up?

Dr. Simon: I was going to say that part of the reimbursement for chemo administration includes the preparation and the mixing and so forth, as well as the practice expense, which includes either a pharmacist or a nurse oncologist, which is the highest paying, the nurse oncologist is the highest pay skilled worker above and beyond the RN, so those costs are captured under the new codes for chemo administration. So those costs are not necessarily lost by the physician.

Dr. McAneny: I would just say that in my office, as I look at my actual costs of doing business, and I add in the costs of my chemotherapy nurses all these things and do it on cost-based accounting, that what ASP plus 6 has done is take Medicare from something that was slightly in the black, to something that's about 3 to 5% in the red. So now I'm cost-shifting to my Medicare patients, instead of cost-shifting

in, that for me does count the 20% of mine who have no co-pays. But I figure, just like I had to take that in as the cost of doing business, so should the CAP vendor.

Dr. Simon: Sure. My only point was that the RUC took that into consideration when they valued the services that oncologists provide, and the panel which is comprised of multi-specialties, were aware of all the sensitivities as it pertains to the specialty type as well as the expertise that's required to provide those services.

Dr. Castellanos: Are there any other comments? Now at the last meeting, we did make several recommendations for competitive bidding on drugs, F1, 2, 3, 4, and 5. And as Dr. Simon said this morning, until the Final Rule is published, we really can't make any comments, but he did say these would be addressed in the final regulation. Would it be acceptable that we just transfer these recommendations that we have made, February 7th? To today's meeting, and have them answered by CMS August 22nd?

Dr. Simon: Yes, that would be fine.

Dr. Castellanos: Are there any other recommendations?

Mr. Kuhn: The only thing I'd like, if I could, is you had made a recommendation earlier about the interim final, and while Terry and Amy are here, I'd like them to hear that as well, so they would be aware of it.

Dr. McAneny: We made and passed on that was requesting that this be, to issue an interim final rule to allow more comments about the CAP programs. [chat] First, I would like to recommend that the CAPs be fully implemented for all specialties and all drugs, without a limited formulary and regardless of the patient ability to pay the co-pay, and with no additional administrative or costs to be visited on the physicians.

Dr. Castellanos: Is there any discussion on that motion? Can you repeat it please?

Dr. McAneny: PPAC recommends that the CAPs must be fully implemented for all specialties and all drugs, without a limited formulary and regardless of the patient's ability to pay a co-pay and with no additional administrative duties or costs to be visited on the physicians.

Dr. Castellanos: Is there any discussion on that? I'll call the vote. All in favor?

[Ays]

Dr. Castellanos: Opposed? Are there any other recommendations?

Dr. McAneny: I have a whole list. [laughter]

??: I'm surprised!

Dr. McAneny: I know you're surprised. [chat] PPAC recommends that the CAP vendors not be allowed to market directly to patients or to sell the physician prescribing data, the pharmacists or anyone else without physician consent. One of my concerns with this is that one of the ways that the vendors may decide to try to control the cost is to market things directly to the patients, say well, you don't really need, Herbatux, blah blah blah, you should use this other thing instead. Therefore the patients can get very confused if somebody's sending them medical information, saying you should do this and you should do that. We all know what direct and consumer advertising has done in other areas. And in the other way, I hear is that they are going to use this to sell physician prescribing information as a revenue stream, because if you're a big CAP provider that's where you make a bunch of money. And I don't really like the idea that someone can take prescribing data and use it to move market share.

Dr. Castellanos: Is there any questions or further discussion? Amy, Dana could you please repeat that?

Ms. Trevas: Yes. PPAC recommends that CMS stipulate that CAP vendors not be allowed to market directly to patients or to sell physicians' prescribing data to pharmaceutical companies or anyone else without the physician's consent.

Dr. Castellanos: Terry, I understand you want to make a comment on that?

Mr. Kaye: Just to clarify and question, you ended that with the phrase "without physician consent." Do you have an example of when you would think it was OK to do the marketing with physician consent?

Dr. McAneny: OK, if the pharmers are interested in doing a post-marketing review and want to collect our data with them for the purpose of doing something like that. Then I would consent to letting my data be used for safety issues if they were going to use it as a way to sell to the pharmers and say hey if you give me an extra one percent off the cost of my drugs, then I'll sell you all these physicians' data. That's a thing that's allowed to them but is not allowed to somebody, is not practical to somebody who chooses to remain in the buy and bill market.

Dr. Castellanos: I'm going to call the question. All in favor?

[Ays]

Dr. Castellanos: Opposed? Are there any other recommendations?

Dr. McAneny: PPAC recommends that physicians be allowed 30 days for submission of claims for drug administration and that the process of claims submission be kept very simple. The original thing says 15 days, and that's just difficult to do for a lot of physician offices to get everything done in 15 days. No other insurance program asks for that. And when you look at the forms of what they're asking for, not only are they asking you to plot out the chemotherapy regimen into the foreseeable future, but they want all sorts of patient demographics, which is frankly none of their business. They want to know what the disease is, they want to know co-factors and this and that and the other thing, and it looked to me like micro-management by these companies, and I don't think that in the name of privacy that they ought to be held access to that data.

Dr. Castellanos: Well that's two different motions. One is the 15 to 30 day change.

Dr. McAneny: And the other one is just that the process of claims submission be kept simple.

Ms. Bassano: The submission of the order of the drug.

Dr. McAneny: The order of the drugs and also on the other side, once you've submitted that claim, then they want you to come back and help them find out who all the secondary insurance is and what the person, whether or not they've paid their claims in the past, and whether or not you have a good track record on collecting from them, etc. I don't want to be their collection agency.

Dr. Castellanos: There is a lot of data that they're asking in that. And I'll be glad to provide that for you. But some of that data, we think is extraneous in our specialty also.

Dr. McAneny: So limit the data selected would maybe be a better way to put it, but simple.

Dr. Castellanos: And I can give you what at least our organization feels is necessary and not necessary and I'll submit that separately to you.

Ms. Bassano: That would be great.

Dr. Castellanos: OK, so we really have two motions on the floor. Dana, do you want to repeat the first one?

Ms. Trevas: PPAC recommends that physicians be allowed 30 days for submission of verification of administration.

Dr. Castellanos: Is there any discussion on that? All in favor?

[Ays]

Dr. Castellanos: Opposed? The second motion.

Ms. Trevas: Actually, I want to ask that you reread the second.

Dr. McAneny: OK. That the process of I guess I'd say prescription submission and claims submission only have limited data requested.

Dr. Castellanos: And I'll provide that as a separate instead of adding it to this motion.

[chat]

Dr. Castellanos: Any discussion on that?

Dr. Senagore: Friendly amendment? Can I just add a phrase at the end to that comment based upon recommendations from affected specialty societies. This way you can send the information directly to them and they can take a look at it.

Dr. Castellanos: I accept that, Barbara do you?

Dr. McAneny: Yeah, I do.

Dr. Castellanos: One more time, Dana, can you read that back to us?

Ms. Trevas: PPAC recommends that the process of prescription submission and claims submissions require only limited essential data, on the basis of the recommendations of specialty societies.

Dr. Castellanos: Any questions on that? I'll call the question. All in favor?

[Ays]

Dr. Castellanos: Opposed.

Dr. Hamilton: Ron, can I ask one thing? Did you clarify—early you mentioned that there were certain specialties that were able to participate in certain parts of the program.

Dr. Castellanos: That's correct.

Dr. Hamilton: Is that the whole program, or just for those—

Dr. Castellanos: That was just in the collection of that data, that Congress mandated OIG to provide by October 1st.

Dr. Hamilton: So those are just for the certain drugs—

Dr. Castellanos: No, certain specialties. I mean we have a cross between specialties. And some of the drugs she uses I use. But I'm not allowed to provide that data, or they're not interested in collecting my data, but they're interested in collecting her data.

Dr. Hamilton: But you would be able to participate in the program, once it's in—

Dr. Castellanos: Yes, but that's not the issue.

Dr. McAneny: They haven't said—it could be one specialty, it could be all specialties, these certain drugs or it could be all drugs.

Ms. Bassano: Just to clarify, the first issue was an Inspector General Report and study that they have to do. The second issue is it will be dependent on which drugs that we are including in the CAP because we got comment on a variety of should it be particular specialties, or as Dr. McAneny was suggesting, should it be all drugs. So once we publish the final rule, it'll specify which particular drugs will be a part of CAP and then—

Dr. Hamilton: So that has yet to be determined.

Ms. Bassano: It has yet to be determined and then [off-mike] imminently. Very soon. Hoping sometime before summer. And that would be, so then also it would be, because as the doctors were talking about, it's not limited to the particular specialty, it would be drugs commonly furnished by that specialty. But if you're in a different specialty and use that drug, you still could elect into CAP for those drugs.

Dr. Castellanos: My point it would be nice if they would collect data from all 20 specialties that use incident to drugs, but they've elected just to limit that to just—

Dr. Hamilton: Well certainly from my perspective, as an endocrinologist, we treat certain types of neoplasms such as pituitary neoplasms that probably are not treated by the oncologist, but they are treated with drugs that would certainly fit into this category. And this program won't do our specialty much good if they don't make the cuts.

Ms. Bassano: Right, so if the particular drugs that you use are included in CAP, then you would have the option of electing it if you wanted to acquire drugs that way.

Dr. Castellanos: You're just excluded from this study. [laughter] Are there any other recommendations?

Dr. McAneny: PPAC recommends that emergency be defined to include patient hardship and rescheduling an office visit due to a delay in delivering the therapy. The reason for that is that those of us who have patients who come from hundreds of miles away, have a daughter who has to leave her work, or take the kid out of school to accompany them, etc., if you say, oops, sorry, your therapy isn't here today or oops you've progressed, and not only have you progressed, and I'm sorry about that but I have to switch your therapy and that means that you have to reschedule all of your life again to come back again tomorrow. That's not fair to patients who live at a distance.

Dr. Castellanos: Is there any comment on that? I'll call the question. All in favor?

[Ays]

Dr. Castellanos: Opposed? I think that's it. We certainly appreciate both of you, Terry and Amy for being here. It was a lively discussion as usual. Again being a urologist, I'm going to take prerogative of having about a five minute break.

Pay for Performance Initiatives: Quality Measures

Dr. Castellanos: Our last talk for today is Pay for Performance. Some of the initiatives, especially some of the quality measures. Dr. Trent Haywood, Acting Deputy, Chief Medical Officer of Clinical Standards and Quality has put together a comprehensive presentation regarding quality measures as they relate to Pay for Performance Initiative. Dr. Haywood joined us on March 7th to discuss the implementation of the Pay for Performance Initiative. Today Dr. Haywood will elaborate on the quality indicators being considered as CMS is committed to coordinating with the AMA to develop effective, clinically valid approaches to payments that reward a high quality of patient care. Dr. Haywood, we're anxious to hear what you have to say.

Dr. Haywood: Thanks for having me again, as we continue this dialog. As alluded to the last time that I was here, we feel and anticipate that we'll continue to have ongoing dialog around this issue called Pay for Performance, or some may call it Value Based Purchasing, where overarching goals are really looking at better use of our resources, with the ultimate goal of improving [interruption] overall quality and outcomes. So today's conversation provides you a little update primarily with some the activity that has occurred, particularly as it relates to some of the measurement activities since the last time that I've spoken with you. Some of the activity that is occurring in the overall marketplace. Before I get started, I did want

to share with you kind of two observations yesterday as I was flying back here in the airport. One observation, I had the pleasure of running into a gentleman that was a veteran and had not actually flown in 38 years, and so as I was going through the security check-out, I noticed that he was looking quite lost to be honest. And he was standing around waiting for some direction and his bags were on the conveyor belt, and he waited and waited and continued to wait, not knowing that he was supposed to carry his bags and move forward, and similarly he got his bags and then just stood there. And literally did know that he was supposed to proceed to the gate. So finally I went over and talked to him and he said the last time he had actually flown was 38 years ago when Uncle Sam had actually cut him loose, and looked like things have changed substantially since the last time he had flown. [laughter] And so I said, wow, it kind of feels like I'm meeting Rip Van Winkle in reality here. [laughter] But what it made me also think about is the way our current health care is structured as we actually take care of patients in comparison to if you look in other marketplaces, how they've become so much consumer oriented and consumer friendly as far as the options are available. Whether be even banking on line, or whether you even have a bank in the sense that now you have virtual banks where there is no true brick and mortars bank. It's all virtual. And similarly, along the continuum, whether it be airline industries and others, and so they raised the question to us as clinicians to really try to move forward to our industry so that it's not left in somewhat of an archaic position. And then the second observation, as I was leaving, I was walking past, so I dropped him off at his gate and I assured him that no, this is where you need to be and just sit tight until they call your flight and you're safe. I was walking back through the bookstore and the bookstore still had on the shelf a book by Dr. Steven Johnson. Do you guys know or remember Dr. Steven Johnson? If you don't recognize that name for a clinical standpoint, you probably will from by the name of the book, which is *Who Moved My Cheese?* Well recognized book on kind of system changes and changes in very short written, it's about 4 characters Sniff and Scurry, the mice, and then the mice people Him and Haw. Whereby it actually starts to illustrate the running around in the maze in the sense of we need to pay attention to different signs as the system changed so that we're not actually caught in this maze. And that's what it somewhat feels about the activity that is currently underway as it relates to healthcare and where we're going with healthcare over all that there's definitely start to be signals out there about system changing and so how can we do this in a way that allow to all to collectively move forward versus kind of running around in this maze. So with that intro,

let me start with the first slide, please. This is a [Debra?] system change when I said, instead of other philosopher's right now, Adams is probably our contemporary philosopher, so let me just read it, it says, "My first act as temporary bosses revamping our project status card codes, red, yellow, and green would be replaced by white, off-white, and eggshell. I have to confess it was embarrassing to realize I only have one idea." And so I was thinking about that in the sense of what we really don't want to be is in the position of us just having one idea and trying to move forward and convince others about this one idea, one trick pony, that we really do want to move forward with physicians collectively on how we can actually achieve our goals of overall improved quality and better use of our resources. This came out approximately 2 weeks ago, May 4, 2005 in the *Wall Street Journal*, a push for performance base pay in health care receives a boost. Medicare is dipping its toes in the water, but even when a gorilla sticks his toe in the water, it still has a ripple effect. Now the reality is obviously, we don't necessarily consider ourselves to be a gorilla, and if we were, I guess we'd be a kinder gentler gorilla [laughter] but there is a reality that we are obviously trying to pursue ways in which we can better utilize the resources that we have available to improve the overall care for both the clinician's perspective as well as from the patient's perspective.

I just want to highlight, because we're going to spend a significant amount of our time on really that second to the right box, the reward desired performance, that we do keep in the backdrop some of the activity that have traditionally had underway and obviously we're strong on the second box, promoting and creating collaboration and partnerships. The quality improvement organizations on providing technical assistance, and really as we continue to move forward, providing beneficiaries and consumers at large, as well as clinicians with the information they need to improve overall quality, and then finally, continue to make certain that as we have our coverage and payment determination that is done is such a way that actually supports that goal. I'm going to skip through some of these quickly. I kept the slide set together just to remind you of some of the activities that we discussed on last time so that you would have kind of this, as Dr. Castellanos stated, a comprehensive slide, or what I would consider a quite large slide set, but really just to keep it all together instead of you having to go back from the one from last quarter. Again, this just quickly says what the pasting environment was, whereby there was a lot of concern about whether or not you could actually do this activity, whether it was going to be cost prohibitive and whether anybody actually cared about the activity. Again, highlighting some of the concerns. It's really about meeting our

expectations and an incomplete assessment currently, and then lacking the appropriate infrastructure under health IT. And then again it continues to be the million dollar question around the business case. And that's the question I'd rather not—the perceived lack of a business case. Is that really an indictment in and of itself, meaning that the failure to actually being able to demonstrate under the current system, a financial reward, is that an indictment of itself, or is that the underlying barrier? This is just to highlight what I illustrated last time. This continues to be one of the concerns about the fact that under the United States of America, by WHO standards, we are ranked number one in expenditures, but ranked 37 as far as overall quality performance. And the backdrop again being after that, the subsequently we also had to areas, crossing the quality chasm and as we continue to move forward, how we ultimately going to cross that quality chasm. And then this is the oft-quoted Beth McGlenn that ran article about how well we're doing in overall quality performance no matter which way you cut it. You looked at overall care, this roughly 55%. If you break it down by type of care, whether it be preventive or acute or chronic is really around that 55%, and if you break it down by functionalities, whether it be screen, diagnosis, treatment, or follow-up, it's still around that 55%. And then other venues that I've been in, another presenter actually juxtaposed that slide to Shaquiel O'Neill shooting free throws, and despite how well we think Miami may do against Detroit tonight, I think everyone that's putting their money on Miami would be quite nervous at the free throw is your barometer of performance. And so I think this highlights, having that juxtapositioned actually does highlight from a professional standpoint that we all want to do much better than that. That we definitely don't want information out there that seems to suggest that we can only do roughly what Shaq can do on a free throw line. Now others actually told me I should say as I digress, other have told me that he actually improves his free throw performance during the play-offs. But I think we want to improve our performance throughout the calendar year and not necessarily only on monumental times of the year.

Dr. Urata: But you know he's won championships [laughter] despite his free throws. And I think we hit home runs despite our free throws.

Dr. Haywood: I think that's an excellent point that we definitely do.

Dr. Urata: But we can do better.

Dr. Haywood: That's actually one of things that Dr. McClellan continues to harp on is that it's not a broad brush in any sense of saying that we're actually inferior across the board, that we're not actually

providing superior performance is that we actually want to do both. We actually want to continue to improve both on the innovative technological sides and how we do that through our courage process, by still maintaining some of that foundation, whether it be preventive care or chronic management of conditions. And this is just quickly highlighting there was some bump, Dr. Steve Jenks one of our colleagues, had alluded in this article that there was some signs of improvement. It wasn't monumental, but there had been signs of improvement. And this article if you're not familiar with it is the converse of that business case whereby it's actually talk about the cost in the system of poor quality. One of the things that we can do along those IOM aims about efficiency is really try to show up those program for sustainability if we can actually stay away from poor cost of quality and being able to root out poor cost of quality. The second bullet is the one that I've highlighted in particular, because if you start to here more and more about some of our activities around management of patients is this notion around 5% of our enrollees consume 47% of the dollars, and 50% only consuming 2%. These are CBO numbers in 2002 and so as you start to hear more and more about some of our activity underway with chronic disease management, things of that nature, it really does start to address this second prong. This one I had previously given to you and I wanted to highlight this one again, given I think a lot of this can actually be assisted, and I'm really looking forward to physician leadership with some of these activity. Whereby if you look at the list of the activities on those, these are all just Part A, looking at just Part A information, so this is internal data that we just ran, looking at Part A and these are our prevention quality indicators. So what you have is a very small number of diseases whereby there's continue to be admissions that if we were able to even conservatively do one out of 20 to one out of 10, there's substantial dollars on the table that could be redistributed so that those middle two columns talk about 638 million or 1.2 billion dollars in a sense of redistribution in the health care system, if we can actually focus on preventing readmissions as it relates to UTIs, dehydration, adult asthma, heart failure and the like. And then just highlighting again the other continued issue that we continue to have is the work that from dormant about variations, in that it's not only a quality problem, but there also seems to be a variation problem whereby the intensity of the services are not necessarily directly related to overall quality or outcomes. This is interesting for those that have interests in not only quality but also have interest in health care disparity as there start to be more and more literature around this notion of is the disparity related to the socio-economic status, is it actually more related to the geography, whereby

there is starting to be literature that suggests that one of the big determinants may be the geography as far as where you actually gets your service that leads to how you well you're going to do as far as outcomes and quality of services. And this again, just to highlight this issue that I raised before about spending Medicare spending and physician workforce. What you can't see from here, because I definitely can't see it despite having glasses is that on the bottom, if you look in the horizontal axis what you have are average expenditures per Medicare beneficiary, and it goes from $3,000 from the left, all the way up to $8,000, and on the vertical axis, what you have are states ranked according to their quality from the work that Dr. Jenks had done with one being at the top and 51 being at the bottom. At minimum, what you come to realize is that this is a scattergram in the sense that the quality is not necessarily related to the expenditures but there's starting to be more and more concern, if you look at the literature about, that there may actually be an inverse relationship, that those that are shown to be the best at improving quality, also seem to be best at using the resources as well, so that you have a low quality seems to go along with inefficiency so to the extent that we can work collectively on actually improving quality, we might actually get better use of our resources overall the system. I'm going to skip this slide, I'd mentioned this before, so let's just go to the next slide and pass that one please. Let me just highlight this again, just reiterating I talked about carbon in the past environment. The current environment is definitely continuing to move forward. I didn't put on these slides but I had mentioned to you that one of the things that we had done is provide information to consumers and so you have consumers that are actually requesting the information. You also have certification boards starting to request performance information so this highlights the lines with the ABIM and NCQA I'm looking at this, but across the board we've had conversations whereby certification boards are starting to ask for more and more performance measures as relates to your recertification. So if the consumers don't get you, and the purchasers don't get you, the certification boards are also interested in, so it's definitely one of those situations where it makes sense from physician leadership to really start getting engaged with this dialog and so that we can move forward in a way that actually benefits physicians overall versus finding out at the last minute that this has come together without the input of physicians. This I highlight in the past where there's some state activity that actually is starting to move forward, so this is Minnesota, Massachusetts and California. I won't spend much time on that just to say that that activity has continued to go forward at the state level and we're monitoring that as well as we try to make certain that to

the extent possible, the federal government is supportive of the activity and not creating more confusion, and so as I talk about the measure, I talk a little bit more about how we're trying to make certain that there's decreased confusion and that it's actually moving forward in a consistent manner. Here's what I did want to highlight. Again, I apologize that it's blurry on this presentation, so let me read this to you. This was a news clip that came out last week. Friday of last week, or the week before.

Dr. Urata: May 13th.

Dr. Haywood: May 13th, thanks. So a week and a half. And it was survey that had been done by Commonwealth Fund. You can go on line and look at Commonwealth Fund, and find out the background of who they all surveyed, but kind of broad brush survey of different participants in the health care marketplace. And what they're topic says is Health Care Leaders Pay for Performance, Most Effective Way to Reduce Health Care costs. And this again, this is consistent with the notion that I was showing on those previous slides whereby I more focus on the performance improvement, more focus on quality may actually use to better utilization of resources and so at the top what you see as the rankings from this survey is 57% said reward more efficient and high-quality medical care is probably the best way to overall reduce the growth and health care expenditures and second next to that which kind of related to that second bullet point I had mentioned about really trying to incentivize management of patients. And so to the extent that we can actually improve our management of patients, we also get better utilization of our resources. This I just want to quickly mention, you can't tell from this, but this is the leap frog group. If you go to their this particular site, this is a site whereby they have a database now with over 100 different Pay for Performance programs that are out there in the marketplace. Some of them public sector, such as some of ours and majority of them are actually private sector opportunities whereby they're starting to test the marketplace more and more around Pay for Performance so this is consistent with the previous slide where the notion is that Pay for Performance may be the way to better use our resources and get overall improvements in quality. And then as you guys are quite familiar with, Medpak came back in March, and made recommendations, Chapter 2 would be in the interest of all of you in quality of care for our Medicare beneficiaries, and then Chapter 4, it talks about strategy improved care, and Pay for Performance, and also the need to recognize the infrastructure and support for that system through information technology and advances in adoption information technology. This was some of the remarks that came from the

administrator highlighting that physician leadership should be complimented for takings steps forward, and this related to the Ambulatory Quality Alliance and I just wanted to stop for a second and mention the Ambulatory Quality Alliance. As what's occurred similarly with our other settings, whereby we've purposely made certain that one of the things that we wanted to do was not to be top down, but actually to be broad based in our activities is that we worked with this entity now called the Ambulatory Quality Alliance. Where we actually worked across the board with stakeholders primarily with physician leadership at the table, the family practitioners, the interns with the American College of Physicians, our sister agency, for Health Care, Research, and Quality, and the health plans that come together on the issue of actually trying to operationalize measures talking about we could actually start if you will, putting our toe in the water and moving forward with the first set of selected measures to really start working with physician groups in a much more broader capacity, but doing it not only from the stake of the federal government but doing in such a way that the private sector is at the table as well, so you don't have physicians being torn between what the public sector and what the private sector is demanding. And so the purpose of this was to allow for that convergence to occur. And so that's now under the umbrella of what's called the Ambulatory Quality Alliance, and for those that are familiar with what we did on the hospital side is exact similar construct whereby we had one process, which is the endorsement process for measures called the National Quality Forum. That's the only entity that does consensus derived measures, but separate and related to that activity is the hospital alliance in that situation whereby the hospital alliance is where we gather round the room and actually rolled up our sleeves and talked with hospital leadership, with clinicians such as the AMA and the ANA as well to get a sense of what is the right way to kind of phase it in and implement that activity and then what is the right messaging. A substantial amount of the activities around messaging so that we don't create confusion both clinicians, persons, but particularly by consumers by providing the information. And similarly that we anticipate, that's going to be same construct with the Ambulatory Quality Alliance as well. I'm just going to quickly give you a snapshot of some of the measures that you probably are familiar with and you have it in your handout. These are the measures. There are 26 measures that came forth from, that were selected from that Ambulatory Quality Alliance. Some are under this umbrella that I listed as prevention measures. And then you see traditional measures as well under coronary artery disease, such as drug therapy for lowering cholesterol, beta blockers, pre and post-op around AMI

and then heart failure management measures. And then obviously there's substantial amount of work that's going on under the diabetes measurement. So you see diabetes measures listed. You see asthma, and then finally the last slide, please. And then the last slide on this particular measurement set is focused around depression, pre-natal care, and then there's two measures that were included around addressing over use that starts off looking at it from the standpoint of antibiotics selection, the use of antibiotics. One of the things that I was asked to do and I think even today this is a fast moving chart, and so if you ask me to come back and look at this chart probably a week from now or two weeks from now, it may actually look different, but I wanted to try to do is provide a very rough just a snapshot of where we think currently some of the specialty measures are and why we actually need to move those along and so what you'll see is to the left, on the left, you'll see some of the specialty listed and then to the right where we anticipate some of the measures are, so you start off—and some of them, to be honest with you, what we've seen is a lot of specialty societies are actually engaged in actually looking at measures and actually moving forward on measures and with guidelines around measures, but they need some assistance on really getting to a level on which we can actually talk about performance measures and to the extent that we can provide that support we're actively engaged in that dialog. And this gives you an example of obviously internists on this particular slide shows that they've been a little further advanced. And then there continues to be more and more variance around some of the specialty societies, and as you have this in your hand out you can look at that as well as to some of the areas whereby, there may be measures in different columns, there may be some that are definitely ready to go out of the box. There may be some that need some refinement, but otherwise are ready to go, for instance if you look at [inaudible] that's listed in that box there, the measure that had traditionally been done at the facility level but there's no reason why those couldn't be done at the individual physician level and so working with [inaudible] you would be able to apply those at the individual physician level and quickly move forward. And there continue to be some that will probably be in the second to the right bullet, where there applicable but need to be developed more, and then finally all the way to the right where you have people that definitely have guidelines but need to work with us on measurement development. This gets into some of the surgical slides that you may have in your handout. And then final slide on this, is that it? There we go, that's the final slide on measure. And it gives you a sense of where some of the gaps are. Obviously what you can tell just by quickly thumbing through that

that internists and those that are subspecialty of internal medicine are probably further along, not than all of the societies, but definitely further along than some. And to be honest, even when I look at this matrix, now I can press into when it was created, I bet you can actually move some of those more over to the left is where you want to go and you can move some of those other things—I see thoracic surgery there where I can see them working that you can definitely slide them over They've gone through the National Quality Endorsement process. They did that not necessarily at the individual physician level, so it would be dialog around just whether or not we'd need to measure [interruption] at the individual physician level. I think this is where the issues continue to be around, is the notion of trying to make certain that we do this in such a way that we maintain trust and credibility in the measurement, that we obviously need trust in the appropriate use of the measures, that we definitely want to avoid any unintended consequences or perverse incentives around the utility of those particular measures. And that must be done in a collaborative spirit that that has to occur with physician leadership and support to make certain that that does occur, as well as what we do by working with the private sector and the public sector, such as in those alliance format so that everyone understands what the limitations are around the measures. I've already talked about from the beginning the reason why we collective we would want to support these activities. He allows us to particularly on the second bullet Lines of Financial Monitor Action Professional Goals of all of us, which is improving the quality and providing better services to all consumers of health care services. I just want to quickly highlight that there's a lot of conversation around the issue of how you should do pay for performance and some of the vehicles for those encouraging quality. This is the one that I particularly wanted to lead for some dialog and open discussion around is that first bullet on what to reward. There's multiple ways of rewarding performance and quality in even the Medpak recommendation we talked about combination thereof whereby one of the things that you can see in one of our demonstrations on the hospital side is a relative quality. And what I mean by that is that if for that particular demonstration, because the goal was at a very rudimentary level, testing the financial incentives by providing financial incentives, does that actually move the curve toward the right and improve quality overall? So testing that hypotheses. And doing it in that construct, what we end up doing, is looking at routes in quality, meaning that in that cohort that was actually participating in that demonstration, their bonus payments, or there will be bonus payments made according to five different DIGs, five clinical conditions. And those are in the top

two deciles per clinical condition will be in the money so to speak, with the one that's in the top decile receiving a 2% bonus on DRG and those that are in the second decile receiving a 1% bonus. That's relative quality and what I mean by that is you've already structured that peergroup or comparison group and you're looking at their quality relative to their peergroup. An absolute threshold is whereby you can actually establish [inaudible] so what do you actually want your performance target to be. An example, just hypothetically could be for your diabetics, what do you think the appropriate performance threshold should be for actually maintaining the patients and the sense of this if you have poor control, what percent of your patients should be within high hemoglobin A1Cs a grade of 9, what would be acceptable? Should that threshold be 80%? What should you have? But by and large, what you're doing is just setting an absolute threshold, and you're not necessarily looking at how many reach above or how many fall below, and you're setting an absolute threshold. And then the last bullet is improvement, whereby you actually look at historical trends, or baseline, and then in subsequent reporting periods, what you actually looking at is improvement over that baseline and again, a lot of people have a great interest in that and particularly at CMS as well, because there's a lot of conversation around there may be where the biggest bang for the buck is in improving in the sense that not only are you looking at the high end of the scale, but you also want to really look at the lower end of the scale in the sense of giving that previous literature that I showed you, if you can actually have them move forward and have better use of better quality over all, there's at least a better use of the resources and so there's a substantial amount of interest on improving as well. Let me stop there, I can't tell where I am in timeframe. Where am I in time? Is that about right for conversation? I wanted to open up to the floor and have some dollar, there's obviously way more slides and we can go into any of the conversation that you have on some of the demonstrations specifically. And I'm open to do that as part of the dialog. But what I did want to do is open the dialog, Dr. Castellanos, if possible on any questions or conversations people may have related to both pay for performance, but also, as we start to move forward, continue to move forward, we've had conversation, continue to always have active conversation with some of the national specialty societies and organizations. But we'd also want to make certain that we really take opportunities where you may see them available to really get at the grass roots level where just talking to specialty societies may not get at all the information we need at the individual practitioner level and so to that extent, I'm open and eager to hear more conversation as well

around how we can actually communicate that and what the appropriate vehicle would be to get input at that individual practitioner level as well. So with that, I thank you and I turn it back over to the chair.

Dr. Castellanos: Dr. Haywood, we certainly appreciate your comments today. Are there any questions from the Council that they have for Dr. Haywood? I can't believe this. Jose?

Dr. Azocar: It was a very comprehensive. I'm impressed by your amount of work, and I'm sure you have considered most of these concerns that I and many other people share. And this will be, when you going to measure the performance, you probably are considering the electronic records and these kinds of things, and there are some concerns about the cost of implementation for the small practices for that. And choosing the technology. I know you have worked on that before. Also in terms of the differing outcomes that you're going to get according the socioeconomic class compliance for the patient and complexity, and these kind of things. More than questions, these are just concern that I'm sure you have considered.

Dr. Haywood: Yes, and thanks for raising the concerns. Absolutely we've taken those into consideration and we will continue to kind physician leadership across the board. And I do, when I say physician, I mean all physicians as defined by Medicare, so nurse practitioners and the like. All these issues, with implementation, that's one of the reasons why we're so supportive of alliances around that issue so that we can make certain that we do implementation a way that actually makes sense on the ground that we are cognizant of those issues as it relates to implementation as it relates to data burden, as it relates to some of the providers that may not have the sophistication as you mentioned as far as EHR. And then on the issue of under served communities, or disparities, or things of that nature, we're also very sensitive to that, but we're looking at that from a positive standpoint, that this actually may provide some support and stimulus from that in the sense of being able to really show the clinicians that are taking care of those populations that are really improving quality can actually receive some support and rewards for actually being able to revive that type of support and management for those patients. So we're definitely looking at those concerns, and we continue to, and there continues to be more and more not only internally through CMS but more and more research around that particular issue as well, with some of our partners from some of our grant authorizing partners as well.

Dr. McAneny: I see two majors problems in trying to implement a Pay for Performance Program. One is that when someone comes to me and they have a brain metathesis I am efficient at taking care of

that if I work as a good team with the primary care doctor they see first, the neurologist, the neurosurgeon, me, the radiation oncologist. It's a team effort. Yet there's no mechanism when you have non-allied physicians who don't work for the same Kaiser like organization that you can ascribe the fact that we very efficiently got that patient taken care of in a very efficient way, to allocate how much should go to me, how much to the neurosurgeon, how much to the primary care doctor, and we need to do that because if it's not an allied situation, there's no distribution point to spend that money among the physicians. So either you have to take all the people who are little independent practitioners and meld them into systems, which restricts patient choice as to which type of system they want to work with and is not practical in a lot of small areas. And the second one is that if we do a really good job of taking care of that person, we're pulling them out of the Part A side. They don't spend 3 weeks in the hospital recovering from something, but the intensity that we have done, and the volume of the services on the outpatient Part B side goes way up. So it seems to me that if you really want to implement something like this, the starting place has to be breaking down the barriers between the Part A pot of money and the Part B pot of money which means some significant legislative work if they're serious about this so that if we do a good job of keeping people healthier and out of the hospital from whatever disease, then we're saving money on the Part A sides, but we're penalizing the Part B side because their volume and intensity goes up.

Dr. Haywood: Let me try to recall both issues and forgive me if I don't. On the first issue, what I believe I heard was the issue of under Pay for Performance whether or not the incentive is such that it actually kind of rewards collective management and management of patients, and two to the extent that it does reward that, whether or not it does it in such a way that's actually distributed in a fair process. Whereby you actually can assign it. I think that that issue is not one that I think is an issue in the sense of just Pay for Performance. What I mean by that is that as it relates to that actually doing performance measures, I think you can do some performance measures you can do at the individual practitioner level, such as process measuring and things of that nature. Even some outcome measures to the extent possible. And then there are other measures that actually would be at a higher level, whereby you actually not necessarily looking at the individual practitioner level, but you're taking it up a step and you're really looking at it from the collective community standpoint, if you will. And I use the word "community" here to talk about management of patient. So I think you can actually address that in the way that you actually

attribute the performance measure and how you go about actually trying to attribute performance measures at the individual practitioner level. The other thing I think to keep in mind is I think is that one of the things we've shown and other activities is that it's a phase in process, whereby we actually do learn from the actual implementation in the process as to what their appropriate limitations are going to be. Not only in terms of the measures, but really in terms of implementation so that we don't have unintended consequence, because we definitely don't want to construct this in such a way that it disincentivizes people to be in a collaborative spirit. And so we hear your concern around that. I think that can actually be addressed in how you actually apply the measure so that you make sure you do the appropriate application of the measure.

On the second issue, as it relates to Part A and Part B silos. I think it's fair to say that we have concerns from the Medicare standpoint about the issue of whether or not physicians providing better quality would negatively impact them. Obviously we don't want physicians to improve the quality in a way that actually disincentivizes them financially. I mean that is the whole purpose for trying to construct this process is to really align our financial incentives with the overall quality improvements and quality targets and so we're eager, in the slide that I showed you, related to Part A and Part B was specifically for that reason, to show that there may be opportunities in the system as we kind of move forward where there could be redistribution or at least looking at that information being there to get a sense of how well physicians are improving quality and how that directly relates to reductions in Part A readmission complications, etc. What we need to do is definitely go ahead and do that. Prove the hypothesis out, provide the information and have all of us work together on that information so that we can do that because I think overall, that would be a benefit not only from a clinician and a [inaudible] standpoint but more important I think from a beneficiary's standpoint that if the financial system is such that it actually supports keeping people out of acute care settings and improve their overall quality, then we would be supportive of that.

Mr. Kuhn: If I may, just make one observation about your first point. And that's the issue of attribution, that is what physician is accountable ultimately for the specific measure. And I think if you look at the 26 that Trent put up there in terms of the ones that came out of the AQA, I think those are a good starter set, where you can really look at a single position that can be accountable for any one of those, but I

think the challenge for all of us and I think the challenge for the people around this table is you work with your specific specialty societies is think through those issues. And I think you're asking the right point. Is are we going to be developing measures in the first round or second round of starter sets ones that there is going to be attribution from one physician to another and where maybe your financial outcome of a quality measure is dependent on someone else, or can we find ones that can be assigned to one individual? And that's a challenge not only for CMS, but I think it's a challenge for all the specialty societies to work with us, to work with one another to help develop those sets. Because as soon as we can grapple with those issues I think they all were better off for it. So it's something we've very sensitive to. And your second point, Trent's absolutely right. We have to look at this holistically, as a total picture. And the physicians are doing a terrific job of reducing costs out there and preventing hospitalizations, etc. We've got to find a way to capture that, not only measure, but capture it. Because I think you're absolutely correct there.

Dr. Leggett: I just want to reemphasize one point in this whole process which is it's historically already documented that physicians in this country don't really adhere to evidence-based guidelines in a systematic fashion, so whatever payment for performance is developed, it has to be evidence-based and outcome-based, so that you don't degenerate into kind of a series of activities that don't improve patient care, and it starts to have physicians doing things simply for the performance pay that are not related to anything that we can put our finger on. So any effort, and I think it would be specialty combined that we do, we really need to link it to evidence-based guidelines that have already been established that are clearly associated with improved outcomes in patient care. And if in fact, Medicare can be a proponent in helping the entire physician base in the country to improve their evidence-based guideline adherence, it would be a win win across the board, I think. That would be my major point on this subject.

Dr. Haywood: Yes. Thanks for that comment. That is exactly [off mike] all of our activities directly that are evidenced-based on [inaudible] scientific value reliable measures. In particular I have shown to demonstrate overall improvement in quality and also overall improvement in outcomes. But that are actionable. In other words actionable, so if we are going to do something as Herb had indicated at the individual practitioner level, we want something that's actionable that the individual practitioner can have some impact on so I think you're right on that and that's exactly where we have and we will continue to stay focused on that area, making sure that it is not activity merely for the sake of just measuring, but

directly related to the current evidence-based, the guidelines and then ultimately the measure derived from that process.

Dr. Urata: Well, I was just going to comment that I think it's laudable that we proceed in the direction we're proceeding in, because I think it's a start and an important thing to do. But I am kind of skeptical that it's really going to change a whole lot of the outcome of the general health of our country, because we still have shortly will have 51 million without adequate health insurance. And that does stress our health care system, particularly in emergency rooms, it leads to cost-shifting and things of that sort, resources going to acute care rather than preventative care, and treating people way past, late in their disease, rather than early in their disease, and although we can help those who are elderly in Medicare system, with these things, it still leaves a significant number of people untreated.

Dr. Senagore: It's hard to be against Mom and Apple Pie. But the devil's always in the details of structurally how you envision this to work. For example, will there be a withhold pool from Part B? There will then be allocated to some presenters for preventative medicine, some presenters to procedures? Within procedures, will you risk stratify them so that if you're doing the higher risk population will that be a different system of predicting outcome versus the lower risk, the UK is well into this with the NHS, looking at surgical procedures, and they have worked for probably ten years now, trying to refine data sets to risk stratify for surgical procedures and still aren't quite there. What will be the reporting mechanism to capture the key data sets that you know that my patients are truly sicker than Greg's? When we operate on them or are you just going to say his morbidity mortality is better, so he gets the withhold pool. I think there is a number of structural things to work through about how this will actually mechanistically occur. The goal is fine. No one's arguing with that. It's just structurally, how do you get into the playing field to compete and do we all get the same scorecard to report on because otherwise, for surgical procedures, the rich will get richer. If you're a big institution, with a sophisticated IT system, you'll be in a better position than a three-person group that can't pony up the data.

Dr. Haywood: Yes, and absolutely again I echo your concerns and you're absolutely right that the devil's in the details and that's part of the reason why we continue to state that we wanted to make certain that we didn't do this in a vacuum; that we actually have physician leadership at the table as we walk through the implementation process. So we exactly don't have that issue, where we have the unintended

consequence of the rich getting richer, that they already have the infrastructure, then we're paying them for the infrastructure that they already had, while the reality is that one, most patients can't get to those institution across the country, and two, it hasn't done much with actually better use of our resources because we've just allocated to that same population. So I agree wholeheartedly. What we've tried to do along those lines is really work with the physician leadership and part of what that may end up being, as I allude to it, is you don't necessarily get there overnight I think is obviously what you've talked about with the UK experience, that you can't just flip a switch and all the sudden we're all performing against each other tomorrow, but we start laying the foundation today to get to that goal as very near term to the extent possible and so that we can have a process whereby we know what the end goal is going to be and then we work collectively towards that goal. And so that's where we are today is really starting that process. Some of it is with demonstration. Some of it is with this vehicle, and somebody turn to this vehicle where we actually go out and work with surgeons and the like to say what is the best way that we can actually start that implementation process. And what that allows us to do is learn from that process as we try to reach that goal of where we might need to modify the process as it relates to implementation.

Dr. Senagore: Just to show you a real world example, the state of New York has benchmarked a five hundred open heart cases as their benchmark for quality. So they've got a program in the state that does [inaudible]. In the city of Chicago, only one of the open heart programs does great in the 500 cases of the 22 or 23 programs. So if you follow that, we have evidence-based medicine. That means we closed down 14 of those programs. Get the other fourteen to 500. I think there's a lot of unintended consequences.

Dr. Haywood: I agree and there's a lot of discussion around the use of that example, I could use the volume as a proxy and even though the fact that there's relationships, it varies according to the different surgical procedures, and there's a lot of issues around, using volume as a proxy, and so while we recognize that there's a correlation, that is not the goal in the sense that if we can actually measure the quality, we should measure the quality, not necessarily look at the volume as the arbitrary cut-off. And so that's why you've continued to hear us talk about measuring the performance and the quality and not necessarily looking at volume in and of itself.

Dr. Senagore: What is the time frame to actually begin to implement this process?

Mr. Kuhn: I don't think there's a particular time frame on actual payment. I think you have a lot of folks at CMS as evidenced by this conversation here, we're looking to move as quickly as we can under this area with a variety of different areas to either look at Pay for Performance, pay for reporting or just begin the greater effort of transparency that's out there. Medpak has opined on that. People on Capitol Hill have opined on that. And in fact some of the many specialty societies we've already talked about it, thoracic surgeons is one and others have come in to talk to us about they're ready to go. So I don't know if there's a specific time portal, but I think it's more than the flavor of the month. I think people are ready to go and many of the groups have stepped up and are ready to start moving forward sooner rather than later.

Dr. Simon: I think, too, the agency is looking at the line already. I know Trent has talked about it, but a microcosm of this looking at the VA system with the NSQIP, National Surgical Quality Improvement Program, where they look at all the various surgical procedures from a variety of VA hospitals, which are both academic based and non-academic based, which are small and large and have been able to restratify. I mean they've had several phases. Phase one of their first study was published ten years ago, had 88,000 patients, which was the largest study produced in the world at that time, where they've been able to look at patients and be able to predict with some degree of accuracy what the morbidity and mortality would be related to a patient undergoing a surgical procedure. It doesn't necessarily, all of their system is a little bit different than in the private payer system, but there is a lot that can be drawn from that work, and so I think it's fair to say that the agency is looking at a variety of information across the broad base of the medical milieu to try to figure out how we should approach and embroach this problem.

Dr. Przyblski: I think that there are two issues that need to be considered separately. One is quality and one is saving money. And I think you're going to have a hard time finding physicians who aren't supportive of quality, clearly. And I do think that evidence-based medicine, as Dr. Leggett pointed out is the starting point of how to measure quality and appropriate outcomes. But I would caution using evidence-based medicine in a couple of different venues. One of them is the assumption that unless you have a prospective, randomized control trial that there is no good evidence that some works or doesn't work. And if you read Sagget's Evidence-Based Medicine text, they clearly describe the fact that there are other classes of evidence that still have some value. That include clinical experience, that include non-randomized but controlled trials, etc. and you can't throw out everything if you don't have the prospective

randomized control trial for one, there are many things in medicine that you can't do that anymore, and for two, even good in theory prospective randomized control trials have their faults, which leads me to two, just because you have a prospective randomized control trial, doesn't mean that that is good evidence. And I participated in developing spinal cord injury guidelines for the AANS and we looked at the [Methyl Premilsyn?] study. It had a lot of argument and debate about this very large multi-center prospective randomized double-glided control study, and the conclusion of our group, which was very controversial, that this at best was class 3 evidence. Yet it was and met Sagget's criteria for class 1 evidence and why is that? It had to do with some of the outcome measures. It had to do with the small differences that were measured. It had to do with the fact that subgroup analyses were done afterwards, without the statistical support of that. So just because you've got the study, if you critically look at it, it really may not have that value. If you look at ECIC bypass, extra-cranial, intra-cranial bypass, very large study done internationally concludes that it is of no benefit. But they examine such a wide disparate population of patients, that the small group that actually could get a benefit in that is lost in the very large group analysis. And so you lose out in helping a specific group of patients. Finally on the savings side, I'm not sure that this is where the saving is going to come from. When I looked at your slide about 5% of enrollees costing the system 47% of the dollars, and I wonder where that happens, and what the focus of that 47% of dollars is. When I look at some of the things that I'm involved in in neurosurgery with Medicare population patients with intra-cranial hemorrhages, I see a lot of resources being spent on those patients, yet if you critically look at what data we have, albeit it's kind of limited, it would suggest that the outcomes are kind of determined by the hemorrhage already and all of the resources we throw at that may or may not make a substantial difference, yet we're still spending the resources. Is there quality data for that? I don't know, but if we're interested in quality, let's look at that. If we're interested in savings, let's look at where the big dollars are being spend and where we can save money, and I don't think that that's necessarily in improving quality at the same time.

Dr. Castellanos: Are there any other questions? Dr. Haywood, I think you'll find that our suggestions and comments beneficial as you continue to develop and refine the Payment for Performance quality indicators. We hope that you'll keep the Council informed of your progress, and please don't hesitate to ask us for help and support. We appreciate what you're doing. Thank you. Now we have two

public testimonies. The first is Dr. Albert Bothe, from the Association of the American Colleges. Dr. Bothe?

Testimony

AAMC

Dr. Bothe: On behalf of the Association of American Medical Colleges, I welcome the opportunity to comment on some of these Pay for Performance issues that you've just been grappling with. Just by way of background, the AAMC represents the 90,000 clinical faculty members who are spread through the hundred and twenty-five medical schools and their associated teaching hospitals in the country. So within the group we have a keen interest in what Medicare does. In terms of service, a median service provided by our group plans is to 24% of Medicare beneficiaries. In other words, of all the patients seen in our group practices, 24% of them are Medicare beneficiaries around the country. And in some departments, obviously, it's going to go much higher than that, up to half or more of an individual department's payer mix can be Medicare. The AAMC has been long supportive of the CMS initiatives that you've heard in terms of quality. In fact, many academic medical centers have been actively involved in the development of evidence-based medicine that you just heard discussed, and also in other initiatives about patient safety and quality improvement. In fact, several academic medical centers are participating in the physician group practice demonstration model that's now underway at ten institutions around the country. We heard the comment about the devil being in the detail. And the AAMC believes there are several important design principles and goals that ought to be taken into account in pay for performance, and these are enumerated in the written testimony that you have at your place. I'd like to just take a minute to go over those. As pertinent to the last comment, we do agree that quality of care and safety should be the primary objective of these initiatives. There'll be some improved cost savings, particularly in the preventative area, but cost savings should not be the primary design characteristic. It should be the safety and quality. We believe the performance measures should be evidence-based, as Dr. Leggett said, broadly accepted, clinically relevant, continually updated to reflect how the literature change, and developed obviously with the physician community. We suggest that the measures should be fully adjusted for case mix, sample size, the age sex distribution, the severity of illness, the number of co-morbidities that patients bring with them, and other aspects of the patient populations that may influence results, particularly in the socio-economic domains.

We think there should be fair and accurate models for attributing care when multiple physicians are involved, so that the right person gets the credit or the debit for these pay for performance measures. The initiative should be flexible enough to assess the performance both at the individual level and of a group, whether it be a three-man group or a 1000-person group so that we can appropriately reward those people. And that physicians have the ability to review and correct the performance data before it's made public, which is symmetrical to the initial design characteristics of the hospital quality reporting effort. As you heard this morning, we're concerned about the differential impact of some of the quality improvement activities. Obviously there will be some costs that are avoided, but there will be numerous episodes where these performance activities will actually increase utilization. The Integrated Healthcare Association in California, and they were referred to in one of Dr. Haywood's slides, actually showed some data of their first year of looking at Pay for Performance initiatives in California between the year 2002 and 2003. And there were 210,000 additional screening activities for cervical cancer, breast cancer, diabetes testing and immunizations. And as you heard this morning, under the current SGR system, would be concern that that type of increased activity by physicians would actually be to their financial detriment, while actually improving the quality of the care delivered to patients. The final general area, we'd like to comment on is that the implementation of many of these initiatives will require resources, particularly health information resources, and the whole area of work redesign, as we develop patient registries, as we develop mechanisms to feedback to the providers, what they're doing and then to track that. So we would suggest for consideration CMS determine how to help physicians invest in these additional resources, whether it be additional software or hardware.

AOA

Dr. Castellanos: Thank you, Dr. Bothe. Does anybody have any questions or comments, concerning his…We appreciate your being here, as usual. Thank you. We have one other organization presenting testimony. Carol Monaco, Deputy Director for Government Affairs, the American Osteopathic Association.

Dr. Monaco: Mr. Chairman, PPAC members, thank you for this opportunity to provide comment. I just have a couple of handouts I'd like to provide you. The American Osteopathic Association commends the Practicing Physicians Advisory Council for addressing Pay for Performance and its promise and

challenges. The AOA recognizes the need to ensure that Medicare spends its resources appropriately. The AOA believes that Pay for Performance and other quality-based measures with the proper focus and resources, have the potential to improve the health of patients. And we look forward to working with the Centers for Medicare and Medicaid Services on this issue. Patient-centered care always has been the philosophy of osteopathic medicine, which is the physician working with the patient acts as a teacher to help patients take more responsibility for their own well-being, to maintain their health and change unhealthy patterns. Osteopathic physicians assist patients in developing attitudes and lifestyles that don't just fight illness, but help to prevent it. The AOA wants to heighten the quality of care that osteopathic physicians provide to patients and strives to set the example by being aggressive in our quest to improve medical standards. George Thomas, our president, accordingly has dedicated his term in office to patient-centered quality care. The AOA is engaged in several initiatives which are included in our written statement and in the hand out that I just provided. And some of those initiatives are the clinical assessment program, the health care facilities accreditation program, and we are collaborating with other organizations dedicated to quality reporting and pay for performance standards. For any quality or performance initiative to succeed, the focus must remain on the patient. We encourage Congress and CMS to encourage that appropriate resources are available for quality and Pay for Performance initiatives to alleviate the potential for program interruptions that ultimately could harm patient care. We have certain concerns and recommendations and I'll go through them quickly. Payment. The Medicare physician payment formula must change. The current payment formula essentially penalizes physicians for providing services that the government promotes. When volume goes up, payment comes down. Improving the quality of care will likely result in greater spending on preventive services. Components of Pay for Performance, such as following clinical guidelines should result in a decrease in volume of other more expensive services, which offset increased spending and preventive care. Any changes to the current Medicare payment methodology must not penalize physicians. I'd like to add that the AOA supports legislation introduced in the House and Senate preserving Patient Access to Physicians, Act, 2005. H.R. 2356 addresses the looming cuts projected for 2006 in the full sustainable growth rate, requiring CMS, beginning in 2007, to use a formula recommended by Medpak to more accurately reflect increases in physician practice costs. Another issue is regulatory reform. Congress and CMS must continue and increase their efforts to reduce the current

regulatory and administrative demands on the physician and hospital community. In crossing the quality chasm, the institute of medicine characterizes regulation as a dense patchwork that is slow to adapt to change. We ought to commend CMS for its efforts to address the current demands on the physician community through efforts like PRIT, MedLearn Matters, Provider Partnerships, the Physician Open-Door Forums, all help in alleviating any confusion or concerns that exist and improving relations with the physician community. However, I'd also like to point out, May 22nd article in the *New York Times* illustrates the complexities of the Medicare Program. According to the *New York Times* article, "the Bush administration is revising a preliminary draft of the 2006 Medicare Handbook. The main tool for educating beneficiaries, after discovering that many statements in the document were inaccurate, misleading or unclear, even to people who've worked in the program for decades. Explain the complexities of the Medicare Program is a challenge for CMS staff. Complying with the requirements is even greater challenge for the physicians. The quality of healthcare suffers when regulatory requirements drain time, money, and resources from patient care. In addition, again, we say that CMS and Congress must ensure that quality and Pay for Performance initiatives do not create demands that take essential time and resources away from actual patient care. Health information technology. The AOA is committed to advancing the development and utilization of information technology to improve the quality and efficiency of health care delivery system. We believe that HIT, if developed and implemented in conjunction with the physician community and other stakeholders, offers great promise. While we support, HIT, how computer technology is used in control in health care raises concerns about the patient's privacy, safety, confidentiality, and the doctor-patient relationship. And also, users of HIT must be aware that recent studies have shown that computerized errors are on the rise. The US Pharmacopeia study found that E-prescribing mistakes accounted for almost 20% of all hospital health care medication errors in 2003. Physician leadership. Physicians must take the lead in developing, updating and implementing any initiative to improve the quality of care. Third party influences could lead to greater loss of physician autonomy, more interference with clinical judgment, added regulatory administrative burdens, the stifling of innovation, and the demise of individualized care. We believe that the use of evidence-based medicine will improve patient care. However, mechanisms must be in place to ensure that the guidelines being used are the most current. In addition, physicians must have the flexibility to use their clinical judgment when providing care to patients.

What may be best for the population overall may not be appropriate for individuals. The consequence could be the undermining of patient-centered, patient-focused care. Patient responsibility. Osteopathic physicians teach their patients to take more responsibility for their own well being, to maintain their health and change unhealthy patterns. Outcomes not only rely on the performance of the physician or hospital, but also on that of the patient. If the patient refuses to follow the specified care, how will the patient's performance affect the payment incentives and cost efficiencies of pay for performance?

The American Osteopathic Association has taken a leadership role in Pay for Performance and quality based measures through several initiatives. Caution should be taken however so that the call for patient-centered, patient-focused care does not become cost-centered, cost-focused care. Clinical judgment and medical decision making should be determined by the patient's needs. Payment incentives should not make the healthcare provider more beholden to the payer of those incentives than to the patient entrusted in his or her care. Current payment policies in addition to third party influences over the practice of medicine, have contributed to the deterioration of health care by devaluing medicine and the physicians who provide it. To reverse this deterioration, physicians must take the lead in developing and implementing any initiative to improve the quality of care, and maintain control over medical information relating to their patients. In addition, patients must bear greater responsibility for their own health care. Only then will health care become truly patient-centered and patient-focused. Thank you.

Dr. Castellanos: We thank you very much, Mrs. Monaco for your comments. Are there any questions? Up until now, we've made most of the recommendations. Are there any further recommendations PPAC wants to present at this meeting?

Dr. McAneny: Of course! [laughter] PPAC recommends that CMS support legislation or otherwise devise a system that allows the transfer of money saved from Part A to Part B when the savings occur due to better outpatient management allowing avoidance of complications and hospitalization or emergency department use. Can't do it? Can I cut and paste? [laughter] [chatter] This is from the Pay for Performance, obviously, PPAC recommends that CMS support legislation or otherwise devise a system that allows the transfer of money saved from Part A into Part B when the savings occur due to better outpatient management allowing avoidance of complications, hospitalization or emergency department use.

Dr. Castellanos: Are there any questions concerning that motion?

Dr. Leggett: I have a question. I don't see how they would actually even calculate that. I understand in theory what you're posing, but at the end of the day I could see them saying that there's never any excess money to pass over. [laughter] Because we can't come to an agreeable amount. I mean the move should be toward what you're saying. I just think it would be incredibly difficult to actually construct it.

Dr. McAneny: I agree that it would be incredibly difficult, but I think if we never look at an attempt to break down those silos of Part A care and Part B care, I mean you could look at the number of times that an asthma patient is hospitalized, you could look at the number of times a COPD ends up on the ventilator. You could look at the number of times that people end up on dialysis versus get their hypertension better controlled. You can look for me and how much neutropenic sepsis I can treat in the outpatient department and keep them from getting admitted. So there would be ways that you could take selected indicators. You probably couldn't deal with the entire Part A Part B system, but if you take some of your indicators, the outcomes that you're looking at could very well be, decrease emergency department use for an asthmatic child, you know, or decreased number of amputations for a diabetic patient because their hemoglobin A1C was better. I'm not suggesting those as the specific indicators, but I'm saying that we should be focusing on some of those, and then looking at the way to try to break down the barrier between Part A and Part B. Because otherwise, we're going to be stuck in the same system where no good deed goes unpunished. If we do a good job at keeping people healthy and they stay out of the hospital, it will save the Part A money, increase our volume and intensity in services and we'll be penalized again. So I figure, toss it back in their laps and see what they come up with. I have great faith in Herb and Ken.

Dr. Castellanos: Dana, can you repeat that motion please?

Ms. Trevas: PPAC recommends that CMS support legislation or otherwise devise a system that allows the transfer of money saved from Part A into Part B when the savings occur as a result of better outpatient management that results in fewer complications, less hospitalization or less use of the emergency department.

Dr. Castellanos: Are there any other questions, discussion? Dr. Urata?

Dr. Urata: I think the money we save would be spent trying to figure that out. I agree with Chris. Too much to bite off.

Dr. Senagore: Just on the other side, though, it is an intriguing concept because if the process works and the theory is that there are less resources used on the hospital side by better preventive care, better management of disease processes, then it may be that a shift of dollars from Part A to Part B may be a way to deal with that. Because on the other side of this can be very problematic, of how do you compensate physicians? Is it going to be CPT-code level? Is there going to be a withhold based on your NPI? And you're going to get a check at the end of the year because you did better? And what if you did really well with diabetes, but all your hypertension patients stroked. So you know a lot about diabetes, you knew nothing about high blood pressure management, you get a wash then? You're at the bottom of the pool for hypertension and you're on the top of the pool for that. So I think that the concept would be intriguing that if the physicians would do their part, to improve the overall quality of the care processes, and there is a savings on the institutional side, then there would be a reason to migrate the dollars.

Dr. Castellanos: Is there any other discussion? I'm going to call the question. All in favor of?

[Ays]

Dr. Castellanos: Opposed?

[Ays]

Dr. Castellanos: I think there were 2 hands I see, opposed? Three? We need a count here. All in favor, could you raise your hand? Six. That's the majority. Are there any other recommendations?

[chatter]

Dr. McAneny: The other one which may or may not be on that device, is that PPAC request that CMS find an equitable way to distribute Pay for Performance gains when multiple unaffiliated physicians are involved in the process, or, select only those measures that can be attributed only to one physician.

Dr. Castellanos: Is there any discussion on the attribution issue, this is what we're talking about?

Dr. O'Shea: Very telling in Dr. Haywood's analogies or his presentation, that he stopped right before it said, and there will be an overall cut. Because the next one was where he was going to find the money to do all this. And so there really wasn't going to be all the sudden, we were going to find the money tree and be printing out more money, what it was was going to happen was that we were going to be taking away, overall, and then we were going to redistribute that. So I have kind of a problem the way it's being phrased. I do think the delineation is part and parcel to best practice, and I don't know how we're

always going to do that, because I do rely on specialists. If I am managing my hypertension very well, it is because I did get a proper stress test and I know that my ejected fraction is good and everything. Am I going to have to do a, sign out at the end? I think that it's maybe going to be simpler than that, Barbara, that they actually have specific goals that they're going to look at it first, maybe as the system becomes more complicated, we'll have to delineate that out, so I'm not sure that we can do that right now and again I think that he was saying in his presentation that they were going to take back, and then dole that out slowly.

Dr. McAneny: And select only those measures that are attributable.

Dr. Castellanos: I'm going to call the question. Is there—I'm sorry, excuse me doctor.

Dr. Senagore: I'm sorry, just follow up on that. What I'm perplexed about will what will be the denominator to distribute the numerator of dollars? Will it be T-codes, RVUs, numbers of warm bodies that are doing the service? I don't know how you're going to attribute these outcomes. Let's say you saved $100 million. How will you know who actually played ball and was responsible party for the savings? And then allocate it back? That is something that I thnk that would be nice to hear where those thought processes are going.

Dr. McAneny: If you want to formulate that into a recommendation, I'll withdraw mine in favor of that because what I'm trying to get at is the same thing. If they're going to pick a measurement, it either needs to be simple enough to be clearly attributable to one physician and one procedure so you can determine the numerators and denominators, or they have to come up with more data in the system to do it. That's what I was trying to get at.

Dr. Senagore: Why don't we make it simple that PPAC recommends that CMS describe at least current concept of methodology to allocate dollars saved from programmatic performance.

Dr. Castellanos: Is there any discussion on that motion? Are you willing to withdraw your motion?

Dr. McAneny: Sure, it pretty much says the same thing. Say yours again.

Dr. Senagore: As if I'd memorized it. [laughter]

Ms. Trevas: PPAC recommends that CMS describe the current methodology proposed to allocate dollars saved from program performance.

Dr. Senagore: To providers.

Ms. Trevas: To providers.

Dr. Castellanos: Are there any other discussion on this motion? I'll call the question, all in favor?

[Ays]

Dr. Castellanos: Opposed? Are there any other recommendations? I'd like to take this opportunity to allow the Council time to review the recommendations for today's presentation. And usually, Dana, you circulate some written copies of these recommendations? So how long will that be, 5 minutes? So we'd like to take a five minute break. [chatter]

Break

Wrap-up/Recommendations

Mr. Kuhn: Thank you again, Dr. Castellanos, for your leadership and for chairing this committee again. Dr. Przyblski, welcome.

Dr. Przyblski: Thank you.

Mr. Kuhn: We appreciate your active participation in the meeting today. And thank you one and all for your participation and your commitment. It shouldn't be as any surprise to anyone, but again, this is called the Practicing Physicians Advisory Committee. We do a lot of acronyms here. We call it PPAC, but I think each and every one of us staff recognize the word practicing, and that you folks are taking time away from your practices and we appreciate that commitment. We appreciate that sacrifice that you make to participate in this process. I think we had a good rich dialog today. And I think you all for that. We got some really good ideas and some good information and as we continue to try to refine our process and provide ways to present things to you and really engage in a dialog and a thoughtful discussion, I think today was one of those and I really do appreciate that. So with that, I have no other parting comments, but again, thank you, safe travels. And I think the next meeting is August, you'll probably announce that.

Dr. Castellanos: August 22nd, that's correct. Ken do you have any comments?

Dr. Simon: No comments other than we do appreciate all the comments and input that comes with providers today and we look forward to continued dialog in the course of the upcoming year.

Dr. Castellanos: And I want to thank all of you for participating here today. I think like Herb, and like Ken, I think we've had a very productive meeting. The CMS staff have really worked hard in preparing such a worth presentation and sharing with us their concerns and requesting the assistance of the Council members to resolve the issues and enhance the regulatory process. We really hope that our

recommendations will be beneficial and utilized to help the Centers for Medicare and Medicaid services to achieve its mission and goals in provision of care and service to its beneficiaries and wide variety of customers and providers. We certainly appreciate the work of the staff, the contractors, who use their many skills and talents and professional acumen to make these Council meetings successful. These meetings really require a lot of work, coordination, and communication, and we thank you all. As Herb stated, the next meeting of the Council will be August 22nd, 2005, and the last meeting for this year, calendar year 2005, is December 5th. That's all I have to say. And I again thank all of you for being here and being part of this meeting. Thank you.